

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CIVIL ACTION NO 16-MD-2738 (FLW) (LHG)

IN RE JOHNSON & JOHNSON : DAUBERT HEARING
POWDER PRODUCTS MARKETING, : JULY 29, 2019
SALES PRACTICES. : VOLUME 6
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CLARKSON S. FISHER UNITED STATES COURTHOUSE
402 EAST STATE STREET, TRENTON, NJ 08608

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1257

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1258

M O R N I N G S E S S I O N

3 | (In open court.)

4 THE DEPUTY CLERK: All rise.

5 THE COURT: Thank you. Good morning.

Everyone may be seated.

7 MS. O'DELL: May it please the Court. We now
8 call Dr. Arch Carson.

10 **ARCH CARSON**, called as a witness on behalf of the
11 Plaintiffs, having been first duly sworn, testified as
12 follows:

14 DIRECT EXAMINATION

15 | BY MS. O'DELL:

16 Q. Good morning, Dr. Carson. Would you please
17 state your full name for the record.

18 A. Arch Carson.

19 Q. Let me ask you, Dr. Carson, to outline your
20 qualifications for the Court?

21 A. I am an Associate Professor at the University of
22 Texas School of Public Health. I'm a physician
23 scientist who specializes in medical toxicology which
24 is a professional practice I've engaged in since 1990.

I'm also a Program Director in the NIOSH

1 Designated Education and Research Center at the
2 University of Texas in Houston

3 Q. Go ahead, Dr. Carson. You may continue.

4 A. Until June I was the program director for the
5 Occupational Medical Residency Program in Houston, and
6 have been for the past 23 years.

7 I have a Ph.D. from Kettering Laboratory in
8 Cincinnati at the the University of Cincinnati,
9 College of Medicine, and an M.D. from Ohio State
10 University.

11 THE COURT: What's your Ph.D. in?

12 THE WITNESS: Toxicology.

13 Q. Dr. Carson, would you share with the Court just
14 a summary of your opinions in this case.

15 A. Well, my first opinion is that Johnson's Baby
16 Powder and Shower To Shower pose a significant health
17 hazard. The epidemiological studies shows me that
18 there is a consistent positive relationship between
19 the genital use of talcum powders and about a
20 30 percent increase in ovarian cancer. Talcum powder
21 clearly migrates through the female reproductive tract
22 when it's applied to the perineum and exposes the
23 ovaries.

24 Inhalation of dust during those applications
25 is a potential secondary route. Talcum powder

1260

1 produces chronic inflammation in the tissues in which
2 it contacts and is sequestered.

3 Johnson's Baby Powder and Shower To Shower
4 contain mineral fibers including asbestos and fibrous
5 talc that intensifies this exposure, and the
6 inflammatory responses including cell growth and
7 proliferation.

8 Johnson's Baby Powder and Shower To Shower are
9 carcinogenic, and I believe the regular genital use of
10 Johnson's Baby Powder and Shower To Shower can cause
11 epithelial ovarian cancer.

12 MR. WILLIAMS: Your Honor, we didn't get a
13 copy of the slides. We just want to make a request we
14 get a copy of the deck.

15 THE COURT: I'll take it as well.

16 MS. O'DELL: It is in your notebook, your
17 Honor.

18 (Pause.)

19 BY MS. O'DELL:

20 Q. Anything further on your opinions, Doctor? If
21 not, we'll discuss your methodology.

22 A. No.

23 Q. Dr. Carson, if you would please, describe for us
24 your methodology in reaching your opinions, please.

25 A. When I was asked to look at this issue, I

1261

1 approached it in the same way that I typically
2 approach this kind of a question, whether it's for
3 litigation purposes or whether it is in my
4 professional practice activities, and I used a
5 step-by-step risk assessment process that is similar
6 to the one that is used by the National Institute For
7 Occupational Safety and Health.

8 As a matter of fact, I stole this graphic from
9 them. It involves identification of the hazard
10 followed by assessment of whether or not there is
11 potential for exposure, then assessment of response to
12 what is known of regarding response to that exposure,
13 and then characterization of the risk. That's what I
14 did in my report.

15 Q. Did you consider the epidemiologic literature?

16 A. I did.

17 Q. Did you consider the literature regarding
18 in vitro studies and in vivo studies?

19 A. Yes.

20 Q. Did you assure yourself that you had made every
21 effort to consider the totality of the evidence?

22 A. That was my intent, yes.

23 Q. You say you formed a risk assessment or you
24 performed a risk assessment. Is that right?

25 A. I did.

1262

1 Q. And you evaluated the evidence and reached a
2 causation opinion?

3 A. I did.

4 Q. The first step, as I understood you -- let me
5 just ask you: What was the first step you undertook
6 to begin your risk assessment analysis?

7 A. Well, I began looking at the published
8 literature on the subject. I also had the benefit of
9 some other documents that were provided to me, either
10 that were produced during litigation activities or
11 that I found in various locations, either my own
12 personal files, those of my colleagues or on the
13 internet, and I began systematically assessing that
14 literature.

15 Q. Did you evaluate the components of Johnson's
16 Baby Powder and Shower To Shower?

17 A. I did.

18 Q. Does pure platy talc exist, in your opinion?

19 A. In my opinion, pure platy talc does not exist
20 except in extreme situations.

21 Q. In your opinion, what are the components of
22 Johnson's Baby Powder and Shower To Shower?

23 A. I have a slide that depicts the components.

24 The major components of Johnson's Baby Powder,
25 of course, is talc, both the platy form, which is the

1263

1 sheet form that gives its slippery and absorbant
2 characteristics that are desirable for Baby Powder.
3 But also fibrous talc which is talc in a fibrous form
4 that is present in almost every container of baby
5 powder.

6 There is also a combination of other
7 ingredients. We know there are certain metals
8 incorporated into the crystals of talc which include,
9 among others, cobalt, chromium, and nickel. And there
10 are fragrance chemicals that are added by the
11 manufacturer to make the product smell nice and feel
12 familiar.

13 The last ingredient is something that comes up
14 over and over in the literature, and that's a
15 component of asbestos that is often found in talc
16 specimens, and we know there has been asbestos
17 historically in talcum powder products, and we
18 continue to find it even to this day as we look for
19 it.

20 Q. What is your opinion regarding the presence of
21 talc fibers or a fibrous talc in Johnson's Baby
22 Powder?

23 A. Fibrous talc is a problem because it produces a
24 significant amount of biological activity, including
25 the potential to cause cancer.

1264

1 Q. Did you review the literature regarding the
2 presence of fibrous talc in talc ore?

3 A. There is literature on talc or a certain amount
4 of information on the presence of fibrous talc versus
5 platy talc in those samples, and it varies widely from
6 geological deposit to geological deposit around the
7 world.

8 I also reviewed analytical reports that were
9 produced as part of this litigation which included the
10 Longo report which I think has already been discussed
11 here, and internal documents of Johnson & Johnson and
12 their talc supplier.

13 Q. Have you prepared slides that compare the
14 differences or pictures of platy talc and fibrous talc
15 and also asbestos?

16 A. Yes, I have.

17 MR. WILLIAMS: Your Honor, we interpose an
18 objection to this slide which is slide No. 3 of the
19 deck as a new opinion. It is not contained in the
20 report. There are no photographs in the report. He
21 did not discuss this particular topic at his
22 deposition.

23 MS. O'DELL: Your Honor, he states in his
24 report that Johnson's Baby Powder and Shower To Shower
25 has platy talc, fibrous talc and the other components

1265

1 he just described. The Shukla paper is on his list
2 and has been on his list from the beginning. This is
3 just a picture of platy talc. It's a demonstrative.
4 He's comparing platy talc to fibrous talc using a
5 photo from Dr. Longo's report.

6 THE COURT: On the Shukla issue, I guess that
7 was part of his report, though, he may not have
8 included the photo. I don't know if there is any
9 dispute that's what platy talc looks like.

10 MR. WILLIAMS: We have no objection to
11 discussing the Shukla study, but the photograph was
12 not ever discussed --

13 THE COURT: I'll deal with Longo in a moment.

14 On the platy talc, is there something about
15 that photo that you would disagree that is not
16 representative and so you would have a problem with it
17 in not having shared that photo before? I don't know
18 what platy talc looks like so I don't know if we would
19 anyway.

20 MS. O'DELL: That's the point, your Honor. We
21 have been talking about platy talc and fibrous talc.
22 Dr. Carson has evaluated those things. This was
23 described in the Shukla paper and --

24 THE COURT: Was this photo in the Shukla
25 paper?

1 MS. O'DELL: It was from the Shukla paper.

2 THE COURT: I'll allow that photo. The Longo
3 one I want to deal with separately.

4 Now, I'll hear from you, Mr. Williams, on the
5 photo from the Longo report.

6 MR. WILLIAMS: It is true that Dr. Carson
7 refers to the Longo report as something that he read.
8 But there is not a discussion of it in his report that
9 discusses this particular topic, platy versus fibrous
10 talc.

11 THE COURT: Is there no discussion in the
12 report on platy versus fibrous? Which exhibit is the
13 report?

14 MS. O'DELL: For the record, it is Exhibit 18.
15 If you look at the report, there are a couple of
16 places he refers to the constituents.

17 MR. WILLIAMS: I think page 5, just above
18 Section D, the words "fibrous talc" appear. There is
19 a reference below to Dr. Longo and to Mr. Hopkins.
20 And then I believe that Dr. Carson has testified that
21 he is not an expert in fibrous talc. That's what he
22 testified to at his deposition.

23 MS. O'DELL: Your Honor, he testified he was
24 not a geology expert. He talks about the
25 classifications by IARC of fibrous talc as a

1267

1 carcinogen. He does reference and rely on Dr. Longo's
2 report. He was asked about fibrous talc asbestos in
3 his deposition. This is well within what he talked
4 about. He talked about the carcinogenic effects of
5 fibers and how they intensify --

6 THE COURT: Let me ask one question. I want
7 to make sure I understand Mr. Williams' objection.

8 Is it on discussion of fibrous talc generally
9 or is it looking at this photo in the Longo report? I
10 want to know how broad the objection is because
11 clearly there's going to be discussion on fibrous
12 talc.

13 MR. WILLIAMS: It's both.

14 With respect to fibrous talc, on page 137 of
15 Dr. Carson's deposition, he was asked the question:
16 "Do you consider yourself an expert on fibrous talc?"
17 And he said, "No," without any caveat or explanation.

18 MS. O'DELL: Your Honor, there is a difference
19 being an expert on the geological formations --

20 THE COURT: Why don't I allow questions on
21 what his expertise in the area of fibrous talc before
22 I rule on this questions. I see you're coming at it
23 in different ways and I want to know what it is.

24 MR. WILLIAMS: Thank you, your Honor.

25 THE COURT: Let's get a couple of questions on

1268

1 that. Experience. You said you are not an expert on
2 fibrous talc. What is your knowledge and what are you
3 planning on testifying about?

4 THE WITNESS: Well, I worked for a number of
5 years evaluating patients who were exposed to various
6 fibrous minerals regarding primarily respiratory
7 effects. I've published in the area of the fibrous
8 minerals. I do not hold myself out as a specific
9 expert in fibrous talc, but I certainly know a lot
10 about it and use it in my everyday professional
11 activities.

12 THE COURT: Whatever that means. Okay.

13 MR. WILLIAMS: I would argue that does not
14 suffice for purposes of getting into what Ms. O'Dell
15 seems to be stepping into with this slide.

16 MS. O'DELL: Your Honor, what we are trying to
17 do and what Dr. Carson wanted to do in his
18 presentation is illustrate for the Court the different
19 components of the products, and then from there turn
20 to the health effects, which, as an occupational
21 medicine expert, that is his area of expertise, not
22 geology. As you know, Dr. Cook and Dr. Krekeler
23 opined on the geology in this case on behalf of the
24 plaintiffs.

25 THE COURT: What does this photo from the

1 Longo report do for me?

2 MS. O'DELL: You want Dr. Carson to answer
3 that question? It just shows you the difference
4 between platy and fibrous talc. They are both talc in
5 chemical composition.

6 THE COURT: Mr. Williams, do you have a
7 problem thinking that photo demonstrates fibrous talc?

8 MR. WILLIAMS: The one on the left, no.

9 THE COURT: The one on the right, from the
10 Longo report, do you think that's a fair depiction of
11 fibrous talc or not?

12 MR. WILLIAMS: I really don't know.

13 THE COURT: Do you know?

14 THE WITNESS: Yes.

15 THE COURT: How do you know?

16 THE WITNESS: I know because it is designated
17 in Dr. Longo's report.

18 THE COURT: That's not enough for me because
19 I'm also testing Dr. Longo's opinions here. That's
20 not been established. So if it's coming from that
21 alone, you don't have any independent knowledge that's
22 what fibrous talc looks like.

23 MS. O'DELL: May I ask a couple of questions?

24 THE COURT: Okay.

25 BY MS. O'DELL:

1270

1 Q. Dr. Carson, did you review the Lockey paper as
2 part of your materials?

3 A. Yes, I did.

4 Q. Is Dr. Lockey one of your former colleagues at
5 the University of Cincinnati?

6 A. Yes.

7 Q. Did he write on fibers and the health effects of
8 fibers?

9 A. Yes, he did.

10 Q. Are you a co-author on some papers with --

11 THE COURT: I want to focus on fibrous talc.
12 This is the difference that I want to have here, and
13 I'm not satisfied at this point. He's talked about
14 certainly dealing with fibrous minerals, as you put
15 it, but not specific experience in fibrous talc.

16 So my question is, before I accept the photo
17 that he's relying on as demonstrating what fibrous
18 talc looks like, when he says it is because it's in
19 the Longo report, and I have not yet accepted what is
20 in the Longo report, I don't know why I would go with
21 that.

22 MS. O'DELL: Your Honor, this is a photo from
23 the Lockey reference that Dr. Carson has just
24 testified to, and it depicts platy talc with an
25 asbestosiform fiber. It is from the literature. It's

1271

1 peer-reviewed. If the Court is concerned about using
2 Longo photos, would you allow us to use these photos?

3 THE COURT: Put the Longo aside. Do you have
4 any objection as to Lockey? We're good?

5 MR. WILLIAMS: We're checking right now.

6 (Pause.)

7 MR. WILLIAMS: Lockey was disclosed, your
8 Honor.

9 THE COURT: We'll go with Lockey. So let's
10 move on. Put aside the Longo photo.

11 MR. WILLIAMS: We would object to having
12 Dr. Carson testifying to the Longo expert report and
13 these photographs to the extent that that's something
14 Dr. Longo should have testified to, and I believe
15 Dr. Carson indicated that is beyond the realm of his
16 expertise. He would just be testifying to something
17 Dr. Longo said in his report.

18 MS. O'DELL: Dr. Longo's report is something
19 that Dr. Carson considered and relied on, but one of
20 the pieces of evidence he relied on with regard to
21 asbestos in the presence of fibrous talc.

22 Your Honor, with your permission, I understand
23 your concern about the photos.

24 THE COURT: You've already got Lockey in
25 there. He's going to talk about what it looks like in

1272

1 the Lockey photo. They don't have a problem. We're
2 good. Let's focus on that.

3 BY MS. O'DELL:

4 Q. Dr. Carson, why don't you briefly share with the
5 Court what is depicted in the Lockey photo.

6 A. The photo on the left is from the Lockey
7 publication in 1981. I was an internal reviewer of
8 that publication. It shows an asbestiform fiber and
9 platy talc in the same slide. The fiber was
10 determined by X-ray diffraction to be asbestos, and
11 that's the reason it is shown on this slide. It's an
12 example of asbestos and asbestiform fibers in talc.

13 Q. Has IARC considered the issue of fibrous talc?

14 A. Yes, it has. And in the 2010 report that
15 included investigation of talc, IARC stated that "talc
16 containing asbestiform fibers and talc not containing
17 asbestiform fibers exists, and the term 'asbestiform
18 fiber' has been mistaken as a synonym for asbestos
19 fiber when it should be understood to be any mineral,
20 including talc, when it grows in an asbestiform
21 habit."

22 That monograph considered talc not containing
23 asbestiform fibers and ranked it a 2B carcinogen,
24 meaning a possible human carcinogen.

25 In 2012 IARC published another monograph which

1 considered asbestos and fibrous minerals, and it
2 included talc containing asbestosiform fibers and
3 classed that as a Group 1 human carcinogen.

4 Q. Finally, is it fair to say fibrous talc is
5 considered a Group 1 carcinogen or a known human
6 carcinogen in the category of asbestos?

7 A. As far as IARC is concerned, yes.

8 Q. Let's turn our attention to heavy metals that
9 are contained in Johnson's Baby Powder and
10 Shower To Shower. Have those metals been evaluated by
11 IARC, also?

12 A. Yes, they have. IARC has also evaluated cobalt,
13 chromium, and nickel and has classed chromium and has
14 classed chromium and nickel both as Group 1
15 carcinogens, and cobalt as a Group 2B possible human
16 carcinogen.

17 Q. What's the proposed mechanism by which metals
18 cause cancer in general?

19 A. Well, it's quite complex. It depends to some
20 extent on what molecules within cells the metals come
21 in contact with, but they are primarily catalytic
22 substances that create electrochemical reactions
23 leading to the generation of reactive oxygen species
24 and cellular damage due to disruption of
25 macromolecules including DNA.

1274

1 Q. Dr. Carson, what's your opinion regarding the
2 fragrance chemicals contained in Baby Powder and
3 Shower To Shower?

4 A. There is a range of chemicals, quite a long list
5 of mostly organic chemicals that are added as
6 fragrances. They are added in trace amounts in the
7 material. Although they contain some recognized
8 carcinogenic substances, in my opinion the
9 contribution of fragrance chemicals to the overall
10 carcinogenicity of baby powder is minor.

11 Q. After you evaluated the components of Johnson's
12 Baby Powder and Shower To Shower, what was your next
13 step in your methodology?

14 A. Well, I looked deeper into literature and I
15 wanted to evaluate the responses to the exposure. So
16 I looked at the epidemiological studies that have been
17 developed regarding the relationship between genital
18 talc use and ovarian cancer.

19 Q. How did you approach your review of the
20 epidemiologic literature?

21 A. I performed essentially a systematic review of
22 the literature trying to search for all available
23 studies, and in all languages that addressed this
24 topic, and then filtered through until I determined a
25 list of relevant publications, evaluated each of them

1275

1 for their study methods, their conclusions, the
2 quality of the studies, and so forth, and then
3 considered them all as a whole.

4 Q. Does this forest plot -- for ease, I've asked
5 you to use Dr. McTiernan's forest plot. Does this
6 forest plot assist you in sort of walking through your
7 evaluation of the literature?

8 A. Well, this is a graphic I borrowed from
9 Dr. McTiernan because it looks much better than the
10 one I had. It depicts exactly the same information.

11 What it shows me is that of the many studies
12 that have been performed, both case-control studies
13 and cohort studies, the vast majority have determined
14 positive relative risks or odds ratios, and the
15 majority of those are statistically significant, and
16 that the odds ratio, the average odds ratio, if you
17 will, is about -- looks to be about a 30 percent
18 increase in risk, and that's consistent over multiple
19 studies since the 1980s up until just last year.

20 Q. We've heard a lot about cohort studies over the
21 last week. Did you in particular review the analysis
22 of the cohort studies that Penninkilampi and Eslick
23 performed in their study?

24 A. I did.

25 MR. WILLIAMS: Your Honor, objection. That's

1276

1 cumulative of the testimony of Dr. McTiernan.

2 MS. O'DELL: Your Honor, this is not a trial.

3 THE COURT: Well, he's going to break them
4 down. She just asked, did you review the analysis of
5 the cohort studies that those two scientists did.

6 Break them down one by one.

7 MS. O'DELL: Yes, your Honor. Mr. Williams
8 has made an objection this is cumulative.

9 Dr. Carson's expert report and his general causation
10 opinion stands on his own, and he needs to be able to
11 have the opportunity to --

12 THE COURT: The question is, if he is using
13 obviously those studies, you've already started the
14 question here about it anyway, to form his opinions,
15 and that's already been done. I'll hear it. But
16 we're not redoing the epidemiology. He is not an
17 epidemiologist.

18 MS. O'DELL: We're not attempting to do that.

19 THE COURT: You are setting a foundation for
20 what's next. Let's go.

21 BY MS. O'DELL:

22 Q. Did you review the Penninkilampi study?

23 A. I did.

24 Q. Specifically, what did Penninkilampi demonstrate
25 in regard to their analysis of the cohort studies

1 specifically in relation to serous ovarian cancer?

2 A. They showed a relationship. When they looked at
3 the cohort studies alone, they showed that there was a
4 significant and positive relative risk associated with
5 serous epithelial ovarian cancer, which is the most
6 common and most deadly form of the disease.

7 Q. What was the amount of the increased risk?

8 A. The odds ratio was 1.25 which represents a
9 25 percent increased risk over baseline.

10 Q. Was that finding statistically significant?

11 A. It was.

12 Q. In addition to the case control and cohort
13 studies, did you also consider the meta-analyses and
14 pooled studies that have been performed on the
15 perineal use of talcum powder literature?

16 A. I did.

17 Q. Does this analysis assist in walking us through
18 your evaluation of the meta-analyses and pooled study?

19 A. Yes. This shows the meta-analyses that have
20 been performed on these data going forward starting
21 back in 1992 with the three most recent --

22 THE COURT: Step back a little from the
23 microphone. There's a lot of feedback.

24 A. -- with the three most recent evaluations being
25 reported in 2018.

1278

1 The meta-analyses universally find a positive
2 relative risk, and they are all statistically
3 significant, and that includes the Terry 2013 pooled
4 study.

5 Q. In evaluating the epidemiologic literature, what
6 methodology did you use to weigh those studies that
7 were statistically significant versus those that were
8 not statistically significant?

9 A. Well, looking at the epidemiological studies
10 individually, I wanted to let the authors speak for
11 themselves and let each study stand on its own. I
12 think the comparison, the forest plot you showed
13 earlier, really tells the story. These are all
14 positive relative risks, and many of them are
15 statistically significant. The consistent positive
16 relative risk is very telling in this kind of area of
17 research.

18 Q. Let's transition now away from epidemiology. I
19 know the Judge wants to hear something new. So let's
20 focus, if we could, on exposure of talcum powder
21 products to the women that used them.

22 A. All right.

23 Q. Do you have an opinion as to whether talcum
24 powder can migrate from the perineum and reach the
25 fallopian tubes and ovaries?

1 A. I do.

2 Q. What's your opinion?

3 A. I think that the female reproductive system is
4 essentially an open channel. If you apply something
5 to the perineal area, it has ready access to deeper
6 structures including the ovaries.

7 Q. Did you review the literature that relates to
8 migration of particles or particulates from the
9 perineum to the ovaries?

10 A. I did.

11 Q. And is this some of the literature you reviewed?

12 A. It is.

13 Q. I know we're going to hear more about that from
14 Dr. Clarke-Pearson tomorrow. But would you briefly
15 describe your evaluation of the evidence you relied on
16 in reaching your opinion that talcum powder can
17 migrate to the fallopian tubes and ovaries?

18 A. There are a number of studies that have been
19 done over the years looking at various kinds of
20 particulate substance and their ability to migrate
21 through the female reproductive system. Some are
22 shown on this slide.

23 The earliest one on the slide being Egli and
24 Newton in 1961 where they looked at the transport of
25 carbon particles through the female reproductive

1280

1 system and noted that transport occurred.

2 In 1979, Venter and Iturralde, they studied
3 the migration of technetium-labeled particles through
4 the reproductive system from the vagina to the
5 peritoneal cavity and ovaries and showed that occurred
6 as well.

7 There have been other studies since notably
8 studies on retrograde menstruation and Halme and
9 colleagues in 1984, that showed that retrograde
10 menstruation occurs frequently in many women.

11 The Kunz article in 1997 studied the uterine
12 peristaltic pump, which is produced by muscular
13 activity in the uterus and fallopian tubes, and showed
14 that sperm traveled much faster through the
15 reproductive system than would be expected based on
16 their motility, and in fact non-motile sperm traveled
17 at about the same rate all the way through the
18 reproductive system.

19 There was a study by Heller in 1996 that
20 showed perineal cosmetic talc usage and the
21 relationship of talc being found in ovarian specimens.

22 Q. Dr. Carson, let me stop you for a moment. Are
23 the carbon particles that have been studied and the
24 other particulates, for example, the cornstarch
25 particulates, and the glove powder study, would they

1 be similar in size as what you would expect with a
2 talcum powder particle?

3 A. Yes. These are all about the same general size
4 including sperm.

5 Q. Did you consider migration animal studies for
6 purposes of reaching your opinion regarding migration?

7 A. I did.

8 Q. Tell us what your evaluation resulted in.

9 A. Well, among others, there were animal studies
10 that were done mostly in rodent species, and it was
11 determined by the authors that rodents really are not
12 a good model of the human reproductive system. As a
13 matter of fact, there is not really a good nonprimate
14 model of the female human reproductive system for this
15 purpose. And so I pretty much discounted animal
16 research trying to look at this issue.

17 There was one study in monkeys that was done
18 by an investigator named Wehner and colleagues that
19 looked at migration in monkeys. They did not find
20 that migration occurred in these monkeys, but the
21 authors still were of the opinion that this was a
22 viable transport mechanism and listed reasons why
23 their study may not have been able to show that.

24 Q. Have regulatory bodies reached a similar
25 conclusion that talcum powder can migrate to the

1282

1 ovaries?

2 A. Yes. Among them, the Food & Drug Administration
3 has reached the opinion that while there exists no
4 direct proof of talc and ovarian carcinogenesis, the
5 potential for particulates to migrate from the
6 perineum and the vagina to the peritoneal cavity is
7 indisputable. And then the Health Canada report, I
8 think you have also heard a bit about, stated:

9 "This evidence of retrograde transport
10 supports the biological plausibility of the
11 association between perineal talc application and
12 ovarian exposure."

13 So both organizations have concurred that
14 transport from the perineum to the ovaries does occur.

15 Q. Now, we've talked about migration of talcum
16 powder through the genital tract. Let's transition
17 and focus on inhalation.

18 What are your opinions about the ability of
19 talcum powder particles to be inhaled?

20 A. A portion of talcum powder that is aerosolized
21 as dust during hygienic applications can be inhaled
22 into the respiratory system. A very small portion of
23 that may enter the bloodstream and be able to
24 circulate to other tissues including the ovaries. I
25 think the potential for that to be a significant

1283

1 exposure is very insignificant, and it is although a
2 secondary route of exposure to perineal application of
3 talc I think it is an extremely minor one.

4 Q. In your report you used the word in regard to
5 talcum powder in the ovary, you use this word,
6 "sequestered." What did you mean when you said that
7 talcum powder becomes sequestered in the ovaries?

8 A. Every time a woman ovulates and the ovary emits
9 an egg into the reproductive system, it leaves an open
10 wound on the surface of the ovary, which then has to
11 heal. And this process repeats itself regularly on
12 usually a monthly basis over decades. If talc is
13 present in the milleau of the ovary when that happens,
14 some of it can be incorporated into that healing sore
15 basically and sets up a cascade of chronic
16 inflammation that many believe is the underlying
17 mechanism for the cause of ovarian cancer due to talc
18 exposure.

19 THE COURT: What's your basis for that
20 opinion, Doctor?

21 THE WITNESS: Of the healing into the ovary?

22 THE COURT: Everything you just testified to.
23 You are not a gynecologist.

24 THE WITNESS: I'm not a gynecologist.

25 THE COURT: What's the basis for your

1284

1 testimony?

2 THE WITNESS: There is literature, one paper
3 that I've cited, that shows the presence of talc
4 within ovarian tissue, and this is a proposed
5 mechanism for its insertion into the ovaries.

6 THE COURT: What's the name of that paper?

7 It's cited in your report, I take it?

8 THE WITNESS: This is one I talked about
9 earlier today. It's in the Heller report, but there
10 are others.

11 BY MS. O'DELL:

12 Q. Would the Cramer 2007 paper also be one?

13 A. It's discussed in there, yes, as a mechanism.

14 Q. Doctor, you are a medical doctor. Correct?

15 A. I am.

16 Q. Not just a Ph.D., but you are also a medical
17 doctor?

18 A. That's correct.

19 Q. And in your practice, do you also treat women?

20 A. I do.

21 Q. In addition to the description that you have
22 given us about talcum powder becoming sequestered in
23 the ovary, describe for us, Doctor, whether the ovary
24 has a clearance mechanism, and describe it in
25 reference to the lung so we can understand that?

1285

1 A. Well, when particles are inhaled into the
2 respiratory system and deposited in the lungs, there
3 is a well-designed system that has developed through
4 evolution that allows the lung to clean itself of
5 these foreign particles that come in from the outside.
6 There are mechanisms all the way from the very deep
7 lung, which involve alveolar macrophages, and in the
8 small and large airways that involves something
9 usually referred to as the mucociliary escalator,
10 which is a mechanical system for pushing things up out
11 of the deep lung to where it is swallowed into the
12 digestive system and can be eliminated from the body
13 in that way.

14 The ovaries have no such elimination system.
15 Really, the only means that they have of eliminating
16 anything from inside that organ is through the
17 lymphatic drainage system, which is a minor
18 contribution to that and not very well developed in
19 comparison to many other organs.

20 Q. In summarizing your opinion earlier you offered
21 the opinion that talcum powder products are
22 sequestered in the ovaries and produce chronic
23 inflammation providing the cellular mechanism for
24 carcinogenesis. Let me ask you, how do carcinogens
25 cause cancer generally?

1286

1 A. Well, a number of different pathways exist and
2 it depends to some extent on the specific carcinogen.
3 But if we look at something like minerals, any
4 carcinogenic process, it is generally recognized it's
5 a two-step process.

6 There is a stage referred to as initiation
7 which involves a genetic change in a cell to produce a
8 mutation or a change in the type of cell that it is.
9 That change of a mutation then must survive and go on
10 to become a viable cell which grows and multiplies,
11 and that growth and multiplication is a step called
12 promotion which allows it to eventually become a
13 recognizable tumor.

14 So both stages must exist, initiation and
15 promotion, in order for carcinogenesis to occur, and
16 the time period between initiation and the recognition
17 of a tumor is referred to as the latency period.

18 Q. In your opinion, Doctor, what is the latency
19 period for the exposure of genital talcum powder and
20 ovarian cancer?

21 A. The latency period for talcum powder exposure is
22 somewhere between 20 and 40 years.

23 Q. Doctor, we have a slide on the screen. Would
24 you mind walking us through, if you will, this process
25 again. What does it mean when a carcinogen is a

1 complete carcinogen?

2 A. A complete carcinogen is one that participates
3 in both the initiation and promotion step of
4 carcinogenesis.

5 Q. Are in vitro studies important in determining
6 the mechanism by which an agent causes cancer?

7 A. Once you have a strong suspicion of a
8 relationship, it's often important to break that
9 process down and look at it biochemically in small
10 steps in laboratory-designed experiments where you
11 could look at the individual steps, manipulate them
12 and understand them biochemically.

13 You then have the potential to put all of
14 those steps from laboratory investigations together to
15 understand the underlying mechanism of what you see in
16 whole animals.

17 Q. Let me ask you this: Did you consider the
18 in vitro studies that address -- and when we say
19 "in vitro studies," do we mean cell studies or cell
20 culture studies?

21 A. Yes.

22 Q. Did you consider the cell studies that evaluate
23 talcum powder?

24 A. I did.

25 Q. Did you develop an opinion as to whether talcum

1 powder causes inflammation?

2 A. Yes, I agree with essentially every investigator
3 who's ever looked at this question that talcum powder
4 is a very strong inflammatory agent.

5 Q. Let me turn to the next slide. Are these the
6 cell studies that you evaluated and considered in
7 reaching your opinions?

8 A. Yes.

9 Q. If you would, Dr. Carson, would you walk us
10 through these studies and the pertinent findings for
11 your purposes of reaching your opinions?

12 A. The important point of this slide is it shows
13 the studies in comparison one with another. These are
14 all studies on human cell lines that are relevant to
15 the question of talc and ovarian cancer. The dose
16 ranges that are studied in these five studies are all
17 similar or overlapping. The time periods that they
18 use for exposure are similar as well. But the
19 findings are important to point out.

20 The Shukla study that we mentioned earlier
21 found when these cell lines were exposed to talc, that
22 there was gene up-regulation of 30 genes that occurred
23 as a result of talc exposure. This was an experiment
24 which they also did in comparison with asbestos
25 exposure.

1 In the Buz'Zard study from 2007, they showed
2 proliferation, neoplastic transformation, which is the
3 early form of carcinogenesis, and increased reactive
4 oxygen species.

5 In the Akhtar study from 2010, they showed
6 oxidative stress through the measurement of lactate
7 dehydrogenase which showed damage to the membranes of
8 the cells, and also increased reactive oxygen species,
9 and the reduction in an important antioxidant
10 substance in those cells called glutathione.

11 Q. Dr. Carson, I'm very glad Vinnie asked you to
12 spell that word. I'm not sure I could have done it.

13 Please continue.

14 A. There was a second Akhtar study a couple of
15 years later in the same cell line that they did a
16 little bit differently, and they were able show DNA
17 fragmentation, oxidative stress, lipid peroxidation;
18 again, reduction in glutathione, an important
19 antioxidant enzyme, and apoptosis, which is programmed
20 cell death.

21 Finally, very recently a study has been
22 published by Fletcher and colleagues that looked at
23 six different relevant cell lines for talc-induced
24 ovarian carcinogenesis. And this study actually used
25 talcum powder as its test agent, and showed a change

1290

1 in the redox balance within the cells with generation
2 of reactive oxygen species and other indicators like
3 interleukins, increase in the important ovarian cancer
4 biomarker CA-125, increase in cell proliferation,
5 decrease in cancer cells apoptosis, which means
6 increased survivability of those cancer cells, and
7 single nucleotide polymorphisms often referred to as
8 SNPs.

9 Q. Did each of these five studies that have
10 considered talcum powder find evidence that talcum
11 powder causes inflammation?

12 A. Yes. These studies universally within the
13 confines of a cell culture study showed the effects
14 that release these immunologic mediators of
15 inflammation, including reactive oxygen species,
16 cytokines, interleukins, and so forth.

17 Q. Were the studies consistent in terms of a dose
18 of talcum powder that was used?

19 A. They were. The doses were consistent and
20 overlapping in all of the studies.

21 Q. In your research did you identify any in vitro
22 or cell studies that show that talcum powder does not
23 cause inflammation at the cellular level?

24 A. No.

25 Q. We talked about fibers already this morning.

1291

1 What is the importance of fibers in talcum powder on
2 the carcinogenic effect of the products?

3 A. Well, fibers, starting with our research that
4 was done after we realized that asbestos fibers were
5 strongly carcinogenic to humans --

6 Q. Excuse me, sir. Is this an illustration that
7 helps describe your opinions?

8 A. Yes.

9 Q. Please continue. I'm sorry.

10 A. What this shows is some of the findings that we
11 now recognize are associated with mineral fibers
12 themselves as much due to their size and shape as to
13 their chemical composition. That was one of the
14 findings that came out of research on asbestos.

15 Many other fibers that have been studied,
16 mineral fibers, show the same kind of carcinogenic
17 effects, perhaps not with the same potency as
18 asbestos, but for the same reason, and that's because
19 of the fiber habit, the shape and size.

20 You see here a talc fiber in a photo on the
21 upper left, which is capable of producing direct
22 genotoxicity as we saw from the cell studies I just went
23 through.

24 In the whole human, when these fibers are
25 encountered by the immune system, one of the responses

1292

1 is for the cells of the immune system to attack it and
2 try to eliminate it from the body.

3 In the photo, in the center at the top of this
4 slide, you see one of these immune cells called a
5 macrophage attempting to engulf a fiber, which is the
6 needle-like structure passing from the upper left to
7 lower right.

8 Q. I think you have a pointer, if it is helpful to
9 you.

10 A. Thank you.

11 This central photo here you see the fiber
12 attempting to be engulfed by a macrophage right here.
13 It is known that because these fibers are very much
14 longer than the macrophage is able to stretch, that
15 they cause injury and frustration to the cell.

16 MR. WILLIAMS: Excuse me, your Honor. None of
17 this, the middle photograph and the left photograph,
18 none of this is in the Doctor's report. This stuff is
19 new.

20 MS. O'DELL: It is not new. He's given
21 opinions about how fibers cause inflammation
22 intensify the carcinogenic effect of talcum powder.
23 It is not required that you include photos,
24 demonstratives, in your expert report, as Mr. Williams
25 knows.

1 So this was clearly outlined in his report,
2 that fibers intensify the carcinogenic effect of the
3 product, and that is what he is describing.

4 MR. WILLIAMS: In fact, the discussion relates
5 to asbestos that is in Dr. Carson's report, but the
6 discussion relating to fibrous talc consists of about
7 two sentences in the report.

8 So it does not give any of this detail, and I
9 believe I heard Dr. Carson testifying about the impact
10 of fibrous talc. He pointed to the middle photograph
11 as an example of fibrous talc leading to certain
12 toxicity. That is not in the report.

13 MS. O'DELL: I don't think that's a full
14 reading of the report, your Honor; not only the report
15 but the deposition. Let me just turn to it.

16 He talks in terms of mineral fibers in his
17 report to include asbestos and fibrous talc. This is
18 on page 7:

19 "All talcum powder has some component of
20 mineral fibers that are toxic to macrophages and
21 intensify the inflammatory response and stimulate cell
22 growth and proliferation."

23 I think that is exactly what Dr. Carson is
24 depicting on the slide. This is page 7, middle of the
25 paragraph, at the bottom of the page.

1 THE COURT: I understand he is talking about
2 the subject. I'm not sure if I understand
3 Mr. Williams' objection to be more where these photos
4 are coming from and what they are actually depicting.

5 Tell me what your objection really is. I know
6 there is not a lot to it that's in there in the
7 report, without not much more discussion.

8 MR. WILLIAMS: Correct.

9 THE COURT: But I also know you took his
10 deposition. I don't know if there is more there.

11 MR. WILLIAMS: This discussion now on the
12 board relates to genotoxicity. I don't think there
13 was a discussion of genotoxicity even in the paragraph
14 Ms. O'Dell just pointed out.

15 Our objection simply is if she could point to
16 the particular page of the report or the deposition
17 where there was a discussion similar to what the
18 doctor is doing now, we would not object.

19 THE COURT: The word does not appear there.
20 That's for sure.

21 MS. O'DELL: What word?

22 THE COURT: "Genotoxicity."

23 MS. O'DELL: Certainly the inflammation
24 cascade that Dr. Carson is describing is included in
25 his report and he testified to it in his deposition.

1295

1 Let me, if I could ask the Doctor to define
2 genotoxicity as he understands it. You will see, your
3 Honor, what he has in his report is exactly what's
4 depicted on the slide, particularly in relation to the
5 component of mineral fibers.

6 BY MS. O'DELL:

7 Q. Dr. Carson, how would you define genotoxicity?

8 A. Well, as depicted on this slide, if you follow
9 the arrows, this central photo goes to the right to
10 this figure that depicts inflammation, and that's the
11 indirect pathway to genotoxicity.

12 My opinion is that the inflammation itself
13 results in genotoxic effects, disruption of DNA,
14 epigenetic effects that dis-regulates transcription
15 and results in viable mutations.

16 MR. WILLIAMS: Your Honor, the only reference
17 to genotoxicity --

18 THE COURT: Page 319 of his deposition?

19 MR. WILLIAMS: That's right. And that line of
20 inquiry had nothing to do with what he testified to.
21 The question was:

22 "QUESTION: Do you know whether there are
23 standards tests for genotoxicity and neogenicity?

24 "ANSWER: There are lots of standard tests,
25 yes.

1296

1 "QUESTION: Doctor Saed didn't use any of
2 those, did he?

3 "ANSWER: Well, he went directly to cells and
4 cultures to see what happened when they were treated
5 with talc."

6 That's the only reference.

7 MS. O'DELL: Your Honor, genotoxicity, as Dr.
8 Carson explained, is damage to the DNA. And if you
9 look at page 10 of his report, at the bottom of the
10 page, under "biologic plausibility" he writes:

11 "Once reaching the target tissues, talcum
12 powder and its constituents initiate carcinogenesis
13 via multiple means, including, inflammation with
14 chemotaxis of inflammatory cells, liberation of
15 cytokines, and reactive oxygen species, inactivation
16 of TP53 genetic modulator, inhibition of DNA repair,
17 and long-term promotion of genetic mutations via
18 continuous inflammation, and cellular growth
19 stimulation."

20 Your Honor, that speaks directly to
21 genotoxicity.

22 THE COURT: The guts of it are there. He
23 doesn't use the terms. Frankly, some of these terms
24 are lawyer-supplied in creating these slides. It is
25 not the language he uses.

1297

1 I do understand present in his report would be
2 something that would certainly deal with the subject
3 matter.

4 Let me see where it goes, and let's move on.

5 I don't know how much more we are doing on
6 this subject.

7 MS. O'DELL: Your Honor, if we could finish
8 quickly. Let me ask Dr. Carson.

9 BY MS. O'DELL:

10 Q. Dr. Carson, in regard to the indirect effect of
11 inflammation, does that cause DNA damage in what ends
12 up resulting in the initiation and promotion of
13 cancer?

14 A. Yes, it does.

15 Q. Do metals contribute to the inflammatory effect
16 of talcum powder?

17 A. Yes, they do.

18 Q. We've talked about the cell studies, *in vitro*
19 studies. Now, let's transition to animal studies that
20 address inflammation.

21 MS. O'DELL: Your Honor, I'll move on from
22 this particular slide.

23 Q. Did you consider the animal studies?

24 A. Yes, I did.

25 Q. Is there evidence in animal studies that support

1 your opinion that talcum powder causes inflammation?

2 A. Yes. I've shown some studies on this slide, and
3 each one includes a quotation from the specific
4 article, the opinions of the authors.

5 The Eberl study from 1948 states:

6 "Incontrovertible evidence of the local
7 irritant action of talcum."

8 That was in comparison with starch or other
9 substances.

10 The Graham and Jenkins article from 1952
11 stated, quote:

12 "Talc was universally damaging and the
13 starches seem to be relatively harmless."

14 In 1984, in the Hamilton study, in which they
15 injected talc into the ovarian bursa of rats, noted
16 that it resulted in papillary transformation and the
17 papillae that resulted may represent early neoplasia.

18 MR. WILLIAMS: Objection. The slide
19 references the Hamilton report. What Dr. Carson just
20 said is not contained in the Hamilton study. He cites
21 a sentence from his report and not from the study
22 itself and it misstates the study.

23 MS. O'DELL: He quotes the findings from the
24 study, your Honor. There are no quotes on there.

25 THE COURT: Mr. Williams said he thinks it is

1 not in the report. He is disputing that is an
2 accurate depiction of the report.

3 MR. WILLIAMS: It's an accurate depiction of a
4 sentence that appears in Dr. Carson's report, but the
5 testimony was just that it was part of the Hamilton
6 study itself.

7 THE COURT: He is saying in his testimony --
8 the Hamilton study noted that it resulted in. He is
9 saying that is what the report said or found.

10 MR. WILLIAMS: Correct. Nor does his report
11 have the sentences that are appearing here on the
12 slide.

13 MS. O'DELL: Your Honor, he has the Hamilton
14 study as part of his reliance materials.

15 THE COURT: The objection is, he is not
16 accurately citing the Hamilton study. What he is
17 saying here is not in fact what the Hamilton study
18 found.

19 That's your objection; correct, Mr. Williams?

20 MR. WILLIAMS: That's correct, and it is not
21 in the report, what Dr. Carson's report states. Those
22 sentences do not appear in the report.

23 MS. O'DELL: There is no requirement that
24 these sentences appear in the report. He cites and
25 references this as part of his reliance materials. I

1300

1 think Dr. Carson was asked about the Hamilton study in
2 his deposition.

3 THE COURT: I guess at this point,
4 Mr. Williams, I will rely on you to bring out the
5 Hamilton study on cross and indicate where it is that
6 he finds it. I'm sure that will be one of your
7 questions.

8 MR. WILLIAMS: Thank you, your Honor.

9 MS. O'DELL: Your Honor, let's put it up on
10 the ELMO.

11 BY MS. O'DELL:

12 Q. Dr. Carson, is this the Hamilton study that you
13 were referring to?

14 A. Yes, it is.

15 Q. Does it indicate that exposure of rat ovaries to
16 talc was accomplished by intrabursal injection?

17 A. Yes.

18 Q. Further, does the summary find there were local
19 areas of papillary change noted?

20 A. Yes, it does.

21 MS. O'DELL: If we could go back to the
22 PowerPoint. I think I may have cut off too early.

23 Q. In regard to the third page of the Hamilton
24 study, do you recall seeing this, Dr. Carson?

25 A. Yes.

1 Q. And it states:

2 "Despite the complexities introduced by the
3 bursal distention, it is a particular interest that
4 papillary changes were seen in the surface epithelium
5 of a proportion of the injected ovaries."

6 Do you see that, sir?

7 A. Yes, I do.

8 Q. Based on that, is what we had on the PowerPoint,
9 does that appear to be an accurate representation of
10 the Hamilton study?

11 A. I believe that was the opinion of the authors,
12 yes.

13 THE COURT: What page are you reading from.

14 MS. O'DELL: On the report page 105 at the
15 lower left-hand corner, your Honor, and it continues
16 on to the upper portion of the right-hand column on
17 page 105.

18 BY MS. O'DELL:

19 Q. In sum, Dr. Carson, do the animal studies that
20 you reviewed and considered in reaching your opinions
21 support a conclusion that talcum powder causes
22 inflammation?

23 A. Yes, they do.

24 Q. Is there evidence in humans that suggest that
25 talcum powder has an inflammatory effect?

1 A. Yes, there is.

2 Q. Why don't you walk us through some of the
3 indications in humans that talcum powder causes
4 inflammation.

5 A. These pictures are not from any of the
6 authorities that I'm citing. These are simply
7 illustrations that have been pulled from the internet
8 to illustrate my points.

9 But it has been known for over 100 years that
10 talc produces granulomatous reactions and inflammation
11 in humans. It used to be very common for surgical
12 gloves to be dusted with talc as a lubricant so they
13 could be donned and doffed easily, and many granulomas
14 developed as a result, adhesions occurred as a result,
15 all the result of inflammation produced by talc that
16 was deposited during surgery.

17 Add to that the fact that these properties
18 once recognized were also used therapeutically. Talc
19 has been used to produce pleurodesis which is
20 essentially injecting talc into the chest cavity to
21 glue the lungs to the chest wall through chronic
22 inflammation and healing to cause those two structures
23 to connect. This is done in patients who have chronic
24 fluid build-up in the chest, and this prevents that
25 from occurring, and so it has been used for its

1 inflammatory properties, specifically for that purpose
2 for many years.

3 The FDA banned talc lubricants from surgical
4 gloves sometime ago, because of the side effects of
5 talc depositing in body cavities during surgery. So
6 we have strong historical evidence of talc producing
7 inflammation in humans.

8 Q. Transitioning from talc causing inflammation to
9 inflammation and ovarian cancer. Are there studies
10 that support a conclusion that inflammation causes
11 epithelial ovarian cancer?

12 A. Yes.

13 Q. Are these some of the few studies -- are these a
14 few of the studies that you read and considered and
15 relied on in reaching your opinion?

16 A. Yes, they are. All of these studies recognize
17 the inflammatory ability of talc and the strong
18 potential connection to ovarian cancer. Actually,
19 these are mostly articles.

20 The Ness article from 1999 is a review article
21 reviewing lots of literature on the subject.

22 The Reuter article from 2010 again is a review
23 article.

24 The Balkwill and Mantovani article from 2001.

25 Q. All of these references support a conclusion

1 that inflammation is associated with epithelial
2 ovarian cancer?

3 A. Yes, they do.

4 Q. In particular, did you consider and rely on the
5 Ness article?

6 A. I did.

7 Q. What did you find, at least in part, important
8 about that particular publication?

9 A. This was a review from 1999, and I've taken a
10 figure from that article here that shows the purported
11 mechanisms by which various factors would influence
12 inflammation in the development of ovarian
13 carcinogenesis and among those talc which was the
14 topic of the review.

15 Q. Let me ask you, Dr. Carson, in regard to
16 inflammation and the presence of inflammation in the
17 reproductive tract, you were asked in your deposition
18 -- you were asked a question very similar to this:

19 Is there a greater inflammation in the areas
20 of the reproductive tract exposed to the greatest
21 quantity of talcum powder?

22 Do you recall being asked that?

23 A. I do.

24 Q. What's your answer?

25 A. The answer is no, and the reason is that the

1 inflammation that occurs depends on residence time in
2 the tissue and the ovaries. As I have described
3 before, talc has the potential to enter the ovaries,
4 and once it's in, it doesn't get out. It causes
5 chronic inflammation over time. Other parts of the
6 reproductive system are continually washed clean by
7 body fluids that flow over them. So talc does not
8 have the opportunity to produce chronic inflammation
9 in those areas.

10 Q. Let's turn our attention now to the inflammatory
11 effect of talcum powder and specifically how that
12 inflammatory effect can be intensified by carcinogens.

13 You state in your report that the presence of
14 known carcinogens intensifies the carcinogenic potency
15 of the product. What did you mean by that statement?

16 A. I meant that having carcinogenic materials as
17 contents adds to the effects that result in cancer. I
18 call that potency. So if you add carcinogenic
19 materials to something that's already an irritant or
20 even a carcinogen, it will just be more carcinogenic
21 than it was before.

22 Q. Did you prepare an illustration that would help
23 depict or demonstrate what you are describing?

24 A. Yes.

25 Q. Why don't you walk the Court through this

1 demonstrative.

2 A. This slide is a simple two-by-two quadrant
3 system that depicts the exposure amount or essentially
4 dose on the horizontal axis with increasing dose
5 moving from left to right and carcinogenic potential
6 or potency of individual materials from bottom to top
7 on the vertical axis.

8 So I think that the most common component of
9 talcum powder which is platy talc has a low potential
10 to produce carcinogenesis but a high exposure because
11 it is most of the product. So it is relegated to the
12 bottom right quadrant.

13 The fibrous form of talc which is present in
14 all of these products is much more potent and has a
15 stronger potential to produce cancer and is still
16 present in a high quantity in these materials, and so
17 it's relegated to the upper right quadrant here and it
18 is the most carcinogenic aspect of the materials.

19 The other materials, potential asbestos
20 content, heavy metals, also are very high potency but
21 are present only in trace amounts in the product and,
22 therefore, have been relegated to a lesser potency,
23 more orangeish than red.

24 The fragrance chemicals that do contain
25 carcinogens but are only present in very minute

1 quantities probably have the least potential of all
2 ingredients in talcum powder to cause cancer. So they
3 have been relegated down to the yellow area, less
4 important.

5 Q. Do all these individual components contribute to
6 the carcinogen issue of the product?

7 A. Yes.

8 Q. Would it be fair to say they contribute to the
9 whole in different relative amounts?

10 A. That's correct.

11 Q. Let me transition and ask you a specific
12 question about asbestos.

13 Based on your review of the literature and
14 your experience and training as an occupational
15 medicine physician, is there any safe level of
16 asbestos?

17 A. No, there is not.

18 Q. And why is that?

19 A. Because any dose of a cancer causing material
20 increases the risk of cancer to some extent. We don't
21 have information to show us that there is a safe level
22 of any carcinogen at this point in time. And so my
23 opinion is any dose of a carcinogen increases the
24 carcinogenic risk by some increment.

25 Q. There was an issue that was raised in the

1 briefing for this Daubert process regarding nickel,
2 chromium and cobalt, the heavy metals we have been
3 talking about. Have nickel, chromium and cobalt been
4 shown in studies to be linked specifically with
5 epithelial ovarian cancer?

6 A. Not that I'm aware.

7 Q. Is that necessary in order for those metals to
8 have a carcinogenic effect in the ovaries?

9 A. It is not necessarily needed to have studies
10 that they are carcinogenic to the ovarian tissue to
11 know that they are carcinogenic elsewhere and have the
12 potential to cause cancer in other tissues as well.

13 Q. And why is that?

14 A. Because cancer causation is a fairly general
15 process, and although some organs seem to fall victim
16 to certain carcinogens, it's because it's where those
17 carcinogens locate and cause their effect, but the
18 carcinogenic process is the same throughout.

19 THE COURT: I want to understand your answer
20 because it was a little bit vague to me. What you are
21 saying is you don't need to have a study to link it to
22 the epithelial cancer. You don't need to know that
23 because you know it causes cancer in other places, so
24 there is no reason why it wouldn't cause it here. Is
25 that what you're trying to say --

1 THE WITNESS: What I'm saying is that raises
2 suspicion there could be a contribution to cancer
3 causation in other tissues if you know it's a
4 carcinogen somewhere else.

5 THE COURT: Other tissues, meaning it could
6 have a possibility or not. What is your testimony?
7 Other tissues doesn't mean anything to me unless you
8 are talking about ovarian.

9 THE WITNESS: I'm talking about ovarian.

10 THE COURT: So use those words.

11 THE WITNESS: Just because we don't have
12 studies linking those metals to ovarian cancer, we
13 still know those metals are carcinogenic for other
14 tissues, and we can assume those same mechanisms that
15 lead to carcinogenesis can operate in the ovaries if
16 the potential for exposure exists.

17 THE COURT: That's what I thought your answer
18 was.

19 BY MS. O'DELL:

20 Q. Has it been demonstrated that the metals nickel,
21 chromium and cobalt cause chronic inflammation?

22 A. Yes. All three do participate in inflammatory
23 reactions.

24 Q. And is that mechanism of inflammation for those
25 metals part of what IARC considered in reaching its

1 conclusion at least for nickel and chromium that they
2 are Group 1 carcinogens?

3 A. Yes, it is.

4 Q. Did you perform a Bradford Hill analysis in this
5 case?

6 A. I did.

7 Q. Did you reach an opinion after having reviewed
8 the totality of the evidence regarding causation?

9 A. Yes, I did.

10 Q. What is that opinion?

11 A. My opinion is that genital application of talcum
12 powder over time raises the risk of ovarian cancer in
13 everyone exposed and causes ovarian cancer in some of
14 the people who are exposed.

15 Q. I put up a slide here. Doctor, I want you to
16 walk through your Bradford Hill analysis briefly for
17 us.

18 Before you do that, is employing the Bradford
19 Hill guidelines something that you regularly do in
20 your work as an academic physician and researcher?

21 A. It is. I also teach it to students.

22 Q. Walk the Court through your Bradford Hill
23 analysis in this situation, please.

24 A. There are in general nine considerations that
25 were published by Sir Austin Bradford Hill in, I

1311

1 believe, 1965, and they have been adopted as a primary
2 method for looking at research evidence and causation.

3 The first is "strength of association." I
4 determined mostly from the epidemiologic studies but
5 also from the cell studies and the chronic
6 inflammation that I determined was always present with
7 talc exposure, that there is a strong association
8 between talc exposure and the development of ovarian
9 cancer. So I felt this particular consideration and
10 evidence for it was compelling.

11 I also looked at the consistency. If you
12 consider the forest plot of the various studies
13 looking at the connection from an epidemiological
14 point of view over time, there is little doubt there
15 is consistency among those studies almost all showing
16 a positive odds ratio or relative risk, and the
17 majority of those being statistically significant
18 studies.

19 So I determined there is consistency of the
20 studies and found that consideration was compelling as
21 well.

22 Specificity is a little less easy to define,
23 but essentially it means that this exposure causes a
24 specific disease and not other diseases, and that
25 there is not a lot of confounding. We know that

1312

1 ovarian cancer occurs at a particular rate in women.
2 What we have shown through research is that it occurs
3 more often in women who use talcum powder for hygienic
4 purposes on a regular basis. So based on that
5 information, I believe the specificity consideration
6 is satisfied.

7 For temporality, which means the exposure must
8 occur before the effect, all of the studies that have
9 looked at this have assessed retrospective talcum
10 powder exposure and the experimental studies as well.
11 So temporality is satisfied here.

12 Q. Did you consider biologic gradient or
13 dose-response?

14 A. I did. Most of the -- certainly, with the cell
15 studies and so forth, we do see dose-response at that
16 level, but in whole humans we also see it in the
17 epidemiology studies, although most of the
18 epidemiology studies were not able to test for
19 dose-response relationship. Several of those that
20 attempted to do that were able to show a dose-response
21 relationship, and among those, the Schildkraut study,
22 the Penninkilampi meta-analysis studies that
23 accumulated data, and the Cramer 2016 and Wu 2009
24 studies.

25 Q. How about biologic plausibility? What's your

1 opinion regarding that particular consideration?

2 A. The numerous authors that have discussed
3 inflammation as a primary mechanism for the production
4 of ovarian cancer make very compelling arguments that
5 fit very well into the research milieu. All of the
6 research that has been done on the occurrence of
7 ovarian cancer and its relationship to talc exposure
8 and talcum powder use. So I felt that biological
9 plausibility was very compelling and well described.

10 The coherence means that the conclusions that
11 are drawn from the research that has been considered
12 do not violate any central scientific laws or
13 understanding, and everything makes sense regarding
14 the biological plausibility, the positive odds ratios
15 in women who have been exposed to talcum powder versus
16 those who haven't. And so the coherence consideration
17 of Bradford Hill is satisfied.

18 The experiment consideration requires that
19 interventions be made or tested that can alter results
20 and explain or confirm the conclusions or mechanisms
21 that have been proposed. We know there are a number
22 of interventions such as tubal ligation that blocks
23 the migration pathway that results in a reduced
24 incidence of ovarian cancer. So that suggests that
25 that theory is correct.

1 And various other experiments similar to that
2 can be stated, things like other surgical occurrences
3 or the use of drugs that prevents ovulation. All of
4 these things reduce the occurrence of ovarian cancer.

5 Q. Did you consider analogy?

6 A. Analogy is coming up with a similar kind of
7 example that you can show there is either a
8 structure-function relationship or strong similarity,
9 and the example of asbestos as a mineral which is very
10 similar to talc both chemically and structurally and
11 has been shown to cause ovarian cancer, I felt was a
12 good analogy, although the chemical composition may be
13 slightly different and the potency for carcinogenesis
14 may be somewhat different. I think it's a good
15 analogy and I believe that talcum powder acts in a
16 very similar way to produce ovarian carcinogenesis as
17 asbestos does.

18 Q. Did you give weight to certain of these factors
19 more than others? Did you weigh them?

20 A. I weighed the strength of association, the
21 consistency of the results, and the well-described
22 biological plausibility most highly in arriving at my
23 conclusions.

24 Q. We talked earlier about a concept called a
25 complete carcinogen?

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1 THE COURT: How much longer do you have? It's
2 11:30.

3 MS. O'DELL: Five minutes. Maybe less.

4 THE COURT: Let's finish that up and take a
5 break.

6 Q. Did you make a determination of what type of
7 carcinogen talcum powder products represent?

8 A. I concluded that talcum powder is a complete
9 carcinogen because it participates both in producing
10 DNA damage at the initiation step and chronic
11 inflammation which is the promotion step. So it does
12 both.

13 Q. Have others agreed with your opinion,
14 Dr. Carson, that there is a cause and effect
15 relationship between the genital use of talcum powder
16 and ovarian cancer?

17 A. Yes.

18 Q. Is the Penninkilampi report one of those -- are
19 those researchers that have agreed with your opinion?

20 A. Yes. This is a meta-analysis reported last year
21 looking at all the same studies that we've considered
22 and have been talking about, and it concluded:

23 "The confirmation of an association in cohort
24 studies between perineal talc use and serous invasive
25 ovarian cancer is suggestive of a causal association."

1316

1 Q. Did Health Canada also consider the question and
2 reach a conclusion regarding whether talcum powder
3 causes ovarian cancer?

4 A. It did. Health Canada determined, based on all
5 of the literature that was reviewed and various other
6 supporting evidence, that available data are
7 indicative of a causal effect between talcum powder
8 and ovarian cancer.

9 MS. O'DELL: Your Honor, absent any questions
10 from you, I have nothing further.

11 THE COURT: Okay. We'll take a break now.
12 You can step down for a couple of minutes as well.

13 THE DEPUTY CLERK: All rise.

14 (Recess.)

15 (Continued on the next page.)

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1 THE DEPUTY CLERK: All rise.

2 THE COURT: Thank you.

3

4 **ARCH CARSON**, resumed.

5

6 CROSS-EXAMINATION

7 BY MR. WILLIAMS:

8 Q. Good morning, Dr. Carson. We haven't met. My
9 name is Bart Williams and I have some questions
10 concerning your opinions. Okay?

11 A. Okay.

12 Q. Dr. Carson, you were retained in this litigation
13 to explain the relationship between the habitual
14 perineal use of talcum powder for personal hygiene and
15 the subsequent development of ovarian cancer in users.
16 Correct?

17 A. I was asked to evaluate that relationship and
18 render an opinion, yes.

19 Q. Your opinion is that "habitual perineal
20 application of talcum powder products causes ovarian
21 cancer in some users and raises the risk of ovarian
22 cancer in all users."

23 Is that correct?

24 A. That is correct.

25 Q. By "habitual," you mean routine use over an

1 extended period of time, months or years. Correct?

2 A. Correct.

3 Q. You cannot get any more specific than that in
4 terms of the exposure to talcum powder, that a
5 habitual user of it would have. Right?

6 A. Well, we can look at it more specifically. But
7 the information that we can develop really doesn't
8 answer that question for us. So in terms of my
9 opinion, I cannot get more specific.

10 Q. One of the basic tenets of toxicology is that
11 the dose makes the poison. That's the old saying.
12 Correct?

13 A. Correct.

14 Q. That means that a substance can be harmless or
15 even be good for you if you are exposed to a small
16 amount of the substance but that same substance can be
17 harmful at higher levels. Right?

18 A. Actually, toxicologists usually interpret that
19 saying as a dose-response relationship meaning that a
20 low dose produces a small effect and a larger dose
21 will produce a greater effect or an effect in more of
22 an exposed population. It doesn't say anything about
23 it being good for you at a low dose.

24 Q. For example, theoretically, water can kill you
25 if you drink too much of it. Right?

1 A. That's correct.

2 Q. Water is good for you?

3 A. You need it to live.

4 Q. So can oxygen, meaning breathing oxygen at a
5 higher than normal partial pressure leads to hyperoxia
6 and can cause oxygen toxicity or oxygen poisoning.

7 Correct?

8 A. Yes.

9 Q. Dose is important. Would you agree with that?

10 A. Yes.

11 Q. We can agree even when it comes to a known
12 carcinogen, a safe level of exposure can be possible.
13 Right?

14 A. I disagree with that. As I've said I think I
15 agree with most scientists that any exposure to a
16 carcinogen increases risk of cancer to some extent.

17 Q. The concept of threshold is a concept you deal
18 with day-to-day in your life as a toxicologist.

19 Correct?

20 A. That's correct.

21 Q. Benzene, for example, is a known carcinogen.

22 Right?

23 A. Yes.

24 Q. IARC classifies benzene as a Group 1 carcinogen
25 to humans. Right?

1320

1 A. Yes.

2 Q. It is related to leukemia as the form of cancer.
3 Correct?

4 A. Correct.

5 Q. You know as a matter of personal knowledge just
6 a few months ago in March of 2019 levels of benzene
7 were elevated in Dear Park, Texas, after a fire at a
8 petrochemical plant. Right?

9 A. They were elevated on one sample out of many
10 over three days.

11 Q. Hourly benzene concentrations on that occasion
12 reached above 180 parts per billion in the areas near
13 Dear Park. You remember that, right?

14 A. Yes.

15 Q. In your opinion, the levels of airborne benzene
16 in the areas surrounding Dear Park did not rise to the
17 levels of a health effect concern. True?

18 A. That's correct.

19 Q. You were actually quoted in the newspaper
20 stating words to that effect; that is, that the
21 benzene levels were not a health effect concern.
22 Right?

23 A. That's correct.

24 Q. With respect to benzene, it is your opinion,
25 there is a level of exposure that is not a concern

1 from a health effects standpoint. Right?

2 A. No, that is not what I said.

3 Q. Do you deny that you said to the Houston
4 Chronicle in March that after this benzene exposure
5 occurred, that you did not believe the benzene levels
6 had risen to a level of "health effects concern"?

7 A. I may have said something to that effect. I
8 don't recall the actual statement that I made.

9 Q. Let's take a look at it. If you look in your
10 book. You should have two books in front of you. The
11 first book has Exhibits A, B and C, and then in your
12 second volume, which is the one I would like you to
13 pull out, now they are labeled as P exhibits. This
14 one is Exhibit Carson 516.

15 A. All right.

16 MR. WILLIAMS: Your Honor, you would be in
17 volume No. 3.

18 Q. See the first page of that is the headline of an
19 article written March 21, 2019, experts:

20 "Benzene levels stoke fears but unlikely to
21 cause health effects." See that?

22 A. Yes.

23 Q. If you turn to page 2 of Exhibit 516 it says:

24 "A UT Health School of Public Health medical
25 toxicologist noted that the standard applied in the

1 recommendation of a shelter in place warning was a
2 conservative one not meant to suggest benzene levels
3 had risen to the level of a health effects concern.
4 Their standard for the shelter in place recommendation
5 was to be absolutely protective of people should a
6 larger concentration of materials be emitted from the
7 plant said Dr. Arch Carson, whose expertise is
8 exposure to industrial and environmental toxins.
9 Fortunately that did not occur."

10 Did they quote you correctly?

11 A. Yes, they did.

12 Q. In the case of benzene in this particular
13 exposure in Texas, you were of the opinion there was a
14 level of exposure that was not a concern from a health
15 effects standpoint. Right?

16 A. I think I need to explain that there was no
17 information that showed that anyone had been exposed
18 to any benzene. This was a sampling result that was
19 designed to be precautionary and to detect a plume of
20 benzene or other chemicals should it start making its
21 way toward a population center.

22 Q. There was a benzene release. Correct?

23 A. There was a release of some benzene, yes.

24 Q. But you don't deny the quotations I just read
25 were in fact made by you?

1 A. I don't deny it.

2 Q. You have written peer-reviewed publications for
3 the proper methodology for estimating exposure levels.
4 Is that right?

5 A. Could you point me toward the publications you
6 are referring to.

7 Q. Let me do some things first.

8 Toxicologists study the safety and biological
9 effects of drugs and chemicals and agents and other
10 substances on living organisms. Correct?

11 A. Yes.

12 Q. As a medical toxicologist, your focus is on
13 humans. Right?

14 A. That's correct.

15 Q. And toxicologists develop methods to determine
16 harmful effects of various substances. Right?

17 A. Yes.

18 Q. They develop methods to determine doses that
19 cause those harmful effects. Right?

20 A. Yes.

21 Q. Toxicologists also determine safe exposure
22 limits. Correct?

23 A. In some cases.

24 Q. Now, take a look, if you would -- I want to show
25 you one of the publications that you have authored.

1 It's in your second notebook. It's Carson 506. It's
2 a 1985 study or publication. Were you in fact one of
3 the authors of this article?

4 A. Yes.

5 Q. Take a look, if you would, at page 1, the first,
6 sentence left-hand column, under "Introduction." This
7 says:

8 "An important step in studies relating to work
9 or health" -- "An important step in studies relating
10 to worker health in industrial exposure is the
11 estimation of mean exposure levels."

12 That's what is in the abstract at the top.

13 Right?

14 A. Yes.

15 Q. "Exposure level" refers to the level that is the
16 amount or the dose of a particular substance that a
17 person is exposed to. Right?

18 A. Yes.

19 Q. In the first sentence -- strike that.

20 An exposure level in this context, the context
21 of the first sentence of your abstract, means the
22 level of worker exposure to chemicals or other
23 quantifiable hazards. Is that right?

24 A. Yes.

25 Q. On page 1, left-hand column, in the first

1 sentence under "Introduction" you wrote, you and your
2 colleagues:

3 "An important step in many occupational health
4 studies is the estimation of the mean level of worker
5 exposure to chemicals or other quantifiable hazards."

6 Right?

7 A. Yes.

8 Q. In your published papers you have suggested
9 specific ways to estimate something called "mean
10 exposure levels." Right?

11 A. Right.

12 Q. Jumping over to the right-hand column on page
13 No. 1 of Exhibit Carson 506, let me direct you to the
14 first full paragraph on that right side. You wrote:

15 "This report suggests some established
16 statistical approaches to estimating category means
17 and standard errors and to quantify variability."

18 That's what you wrote?

19 A. Yes.

20 Q. What are "category means"?

21 A. Means are the arithmetic average of exposures
22 and categories would be different exposure groups
23 however they are determined. So you would estimate
24 the arithmetic average exposure to those individual
25 groups.

1326

1 Q. Now, for purposes of formulating your opinion in
2 this case, I take it you did not estimate category
3 means. Right?

4 A. In what context? I didn't catch your question.

5 Q. For purposes of formulating your opinion in this
6 case, I take it you did not estimate category means of
7 exposure for women who use talcum powder?

8 A. No, I didn't manipulate the original data. I
9 let the authors of those original studies and the
10 meta-analyses do that for me.

11 Q. You did not estimate standard errors for dose
12 categories; did you?

13 A. That's correct. Although they were presented in
14 some cases.

15 Q. You did not quantify dose variability yourself?

16 A. I noted it as an issue.

17 Q. You did not quantify it yourself. Correct?

18 A. I did not.

19 Q. You did not do any modeling or assessment of the
20 quantity of baby powder that was involved with daily
21 use. Is that right?

22 A. I did do some back of the envelope calculations
23 to get an idea of roughly the amount of substance we
24 were talking about.

25 Q. Take a look at the red notebook there that

1 contains your previous testimony.

2 MR. WILLIAMS: Your Honor, permission to read
3 from page 231 of Dr. Carson's deposition testimony --
4 actually 232, lines 8 through 12.

5 THE COURT: Okay.

6 BY MR. WILLIAMS:

7 Q. (Reading.)

8 "QUESTION: You did not do any modeling or any
9 assessment of the quantity of baby powder that was
10 involved with daily use. Is that right?

11 "ANSWER: No, I relied on those others."

12 That was your testimony. Correct?

13 A. Yes.

14 Q. Now, you relied on the authors of the primary
15 studies for any information concerning dose. Right?

16 A. That's correct.

17 Q. You do not know as you sit here today and you
18 cannot assist the Court in determining how much talcum
19 powder any particular woman applies each time she uses
20 a talcum powder product. Right?

21 A. If you would like me to assist the Court in
22 understanding that, I do have opinions about that, and
23 I have, as I mentioned a moment ago, done some back of
24 the envelope calculations, which I have not published
25 and would not because they are just that, they are

1 estimates. I have done them.

2 Q. You have stated that it has been difficult to
3 estimate exactly the quantity of talcum powder
4 administration during personal hygiene activities. Is
5 that right?

6 A. That's correct.

7 Q. There is no standard dose as there would be, for
8 example, for a prescription medication. True?

9 A. That's correct.

10 Q. It is difficult to determine the dose or the
11 quantity of talc to which perineal talc users have
12 been exposed. Right?

13 A. I think it is difficult, yes.

14 Q. Now, duration and frequency are the only
15 surrogates that we have for dose according to the
16 literature. Correct?

17 A. Those are the principal surrogates for dose that
18 have been used in the epidemiological literature
19 regarding this issue, yes.

20 Q. You have testified that duration and frequency
21 are the only surrogates we have for dose; have you
22 not?

23 A. As far as I know, that is the case.

24 Q. You cannot tell us how much talc actually
25 reaches the ovaries from any given application of

1 talc. Right?

2 A. That's correct.

3 Q. And that is because that dose has not been
4 quantified. True?

5 A. That's true.

6 Q. It has not been quantified by you?

7 A. Correct.

8 Q. It has not been quantified by any of the studies
9 that you have reviewed in preparing for your opinions
10 here. Right?

11 A. That's correct.

12 Q. You have not determined a threshold level of
13 exposure to talcum powder products that in your view
14 causes ovarian cancer. Correct?

15 A. I believe I testified I don't believe there is
16 one.

17 Q. In forming your opinion, you have not determined
18 a level of harmful exposure to talcum powder products
19 that causes ovarian cancer. Correct?

20 A. I testified that any talcum powder raises the
21 risk of ovarian cancer and may in one person in a
22 million or more cause ovarian cancer.

23 MR. WILLIAMS: Permission to read from page
24 354 of Dr. Carson's deposition.

25 THE COURT: All right.

1330

1 MR. WILLIAMS: Line 24, through page 355, line
2 4.

3 Q. (Reading.)

4 "QUESTION: So in forming your opinion,
5 Dr. Carson, you have not determined a level of harmful
6 exposure to talcum powder products that causes ovarian
7 cancer?

8 "ANSWER: That's correct."

9 Q. Dr. Carson, your opinion in this case is that
10 any perineal application of talcum powder increases a
11 woman's risk of developing ovarian cancer. Right?

12 A. Yes.

13 Q. You believe that a zero threshold approach is
14 proper until we have more information. That's your
15 belief. Right?

16 A. Yes, I do.

17 Q. You have told us that the reason -- the reason
18 that you are using a zero threshold approach in this
19 matter is not because you have actually seen studies
20 saying that perineally applied talc in any amount is
21 cancerous. Right?

22 A. Would you repeat that question?

23 Q. Surely. I want to be precise.

24 The reason that you are using a zero threshold
25 approach in this matter is not because you have

1331

1 actually seen studies saying that perineally applied
2 talc in any amount is cancer causing?

3 A. I would disagree with that statement because I
4 have seen epidemiologic studies that define a
5 dose-response relationship to an increase in ovarian
6 cancer related to talcum powder use.

7 Q. It is your opinion that "there is no threshold
8 of exposure for risk, and because of that you are
9 correct to use a zero threshold approach until we know
10 more about the possibility of a threshold below which
11 exposure would be safe."

12 Those are your words. Right?

13 A. That's correct.

14 Q. And at the current time, according to you, we do
15 not have information concerning an exposure level
16 below which this product, talcum powder, would be
17 safe. Right?

18 A. That's right.

19 Q. So you are actually testifying in this case that
20 any talcum powder use in the perineal area increases a
21 woman's risk of ovarian cancer because you do not have
22 a dose at which harm occurs. Right?

23 A. There is no threshold dose that is known and,
24 based on what's known about carcinogenesis, any
25 exposure results in some increase in risk. So that's

1 my opinion.

2 Q. As a matter of methodology for toxicologists
3 analyzing a substance, isn't the scientific inquiry
4 supposed to be about whether a particular dose level
5 can cause harm?

6 A. No, not at all. We see lots of different
7 knowledge and there are many blanks and gaps in our
8 understanding. So many pieces of research, many new
9 pieces of data fill in multiple areas of gaps in our
10 knowledge, not just related to dose.

11 Q. Let me ask you this, Doctor: You do not know
12 one way or the other whether courts in this
13 jurisdiction have accepted or rejected this no safe
14 level or no threshold model for substance exposure
15 that you are advancing in this case, do you?

16 MS. O'DELL: Your Honor, I would object to the
17 degree it calls for a legal conclusion. Dr. Carson is
18 not here to testify what courts have ruled or not
19 ruled in this jurisdiction, so I would object to the
20 question.

21 THE COURT: I'll sustain that.

22 BY MR. WILLIAMS:

23 Q. Let me ask it this way: Does your conclusion,
24 Doctor, that there is no safe dose for application of
25 talcum powder fly in the face of the toxicological law

1333

1 of dose-response; that is, that the dose makes the
2 poison?

3 A. No, it doesn't. It's entirely in keeping with
4 that.

5 Q. Isn't it true one thing you would need to have
6 in order to figure out the threshold risk for talcum
7 powder or any other substance is dose information?

8 A. Yes. I think that would be true.

9 Q. Your opinion is we don't have dose information
10 to combine with the epidemiologic results. True?

11 A. We do have dose information in terms of
12 frequency and duration as you mentioned before.

13 MR. WILLIAMS: Permission to read, your Honor?

14 THE COURT: Yes.

15 Q. Let me direct your attention to page 325 of your
16 deposition, line 7, through 326, line 10:

17 "QUESTION: Did you make any attempt to
18 extrapolate a de minimus risk level?"

19 There is an objection.

20 "ANSWER: I did not. It would be nice to be
21 able to do that considering that most of us have had
22 talcum powder exposure of one sort or another during
23 our lives, and it is something that seems to have been
24 felt to be very useful. So it would be nice to be
25 able to that exercise, but I haven't -- I have not

1 been prevented -- presented with the information to
2 approach that nor am I aware of anyone else who's been
3 able to do that.

4 "QUESTION: What information would you need
5 that you don't have?

6 "ANSWER: Well, we need dose information,
7 first of all, which we don't have, to combine with the
8 epidemiologic results. We need to define the
9 mechanistic issues better than they are currently, and
10 at that point I think we would be able to make some
11 strong conclusions regarding potential thresholds of
12 hazard doses."

13 That was your testimony. Right?

14 A. Yes, I agree with that.

15 Q. Your opinion is that we do not have dose
16 information to combine with the epidemiologic results,
17 as you testified in your deposition. True?

18 A. That dose information I'm talking about is not
19 doses associated with the epidemiologic studies. It's
20 doses from other sources that we could combine with
21 information that we have from the epidemiologic
22 studies to arrive at conclusions regarding thresholds.

23 Q. But you don't have that. Right?

24 A. I don't have that.

25 Q. In addition to information on dose, you believe

1 that in order to figure out the threshold risk level
2 for talcum powder, you would need, as you said in that
3 testimony a moment ago, a better definition of
4 mechanistic issues than we currently have. Right?

5 A. Yes.

6 Q. And the mechanistic issues that you were
7 referring to refers to the biologic mechanism through
8 which talcum powder purportedly could cause ovarian
9 cancer. Right?

10 A. Yes.

11 Q. And we don't have that. Right?

12 A. We have a lot of it. We don't have enough to be
13 able to predict thresholds for exposure risk of cancer
14 and ovarian cancer.

15 Q. What you said in your deposition was that we
16 would need to define the mechanistic issues better
17 than they are currently. Right?

18 A. In order to determine safe exposure thresholds.

19 Q. Fair enough.

20 Let's sum this up. You do not know the amount
21 or dose of talc to which a woman is exposed at the
22 time she uses talc perineally. Right?

23 A. Not for any one woman, no.

24 Q. You do not know the amount of talcum powder that
25 actually reaches the ovaries from any given

1 application of talc in the perineal area?

2 A. That's correct.

3 Q. You have not calculated the threshold level of
4 harmful exposure to talc?

5 A. That's correct.

6 Q. You have not determined the level of exposure to
7 talcum powder products that is required to cause
8 ovarian cancer. Right?

9 A. I think that any exposure to the ovary increases
10 the risk of the cancer.

11 Q. In forming your opinion, Dr. Carson, you have
12 not determined a level of harmful exposure to talcum
13 powder products that causes ovarian cancer?

14 A. I determined that any exposure raises the risk
15 of ovarian cancer.

16 MR. WILLIAMS: Permission to read, your Honor.

17 THE COURT: Yes.

18 MR. WILLIAMS: Page 354 of Dr. Carson's
19 deposition, line 24, through 355, line 4.

20 Q. (Reading.)

21 "QUESTION: So in forming your opinion,
22 Dr. Carson, you have not determined a level of harmful
23 exposure to talcum powder products that causes ovarian
24 cancer?

25 "ANSWER: That's correct."

1 Despite all of the things that you have not
2 done, as a matter of methodology, you opine in this
3 case that any exposure to talcum powder can cause
4 ovarian cancer. True?

5 A. That's correct. And in the next response to the
6 next question in my deposition, that's exactly what I
7 said.

8 Q. I'm aware.

9 Do you believe that the failure of a
10 toxicologist to conduct a dose assessment is important
11 as a matter of methodology?

12 A. It can be in some circumstances.

13 Q. Now, your expert opinion was excluded under the
14 Daubert standard in a federal court in Texas in the
15 matter of Berleson v. Texas Department of Criminal
16 Justice; was it not?

17 A. Yes, it was.

18 Q. Part of the reason that the Court excluded your
19 opinion in Berleson was because you failed to conduct
20 a dose assessment. True?

21 A. The explanation of that is fairly complicated.
22 But it was -- it in part related to conducting a dose
23 assessment, yes.

24 Q. In the Berleson matter you opined a plaintiff
25 had been exposed to a sufficient level of thorium dust

1 to cause his respiratory track cancers. Do you
2 remember that, yes?

3 A. Yes.

4 Q. Your opinion was excluded because you did not
5 calculate the level of the plaintiff's exposure.
6 Right?

7 A. To some extent, yes.

8 Q. And your opinion was excluded because you did
9 not calculate a threshold level of harmful exposure
10 required to cause cancer by reason of exposure to
11 thorium. Correct?

12 A. That's not entirely true; and being out of
13 context, as it is, I think I can explain some more
14 detail regarding that that would bring the context to
15 that decision.

16 Q. Just so we're clear, and without getting into
17 the detail, you can do it on redirect examination, I'm
18 sure, but my question is simply this: The opinion
19 that excluded your testimony on Daubert grounds
20 excluded your testimony in part because you did not
21 calculate the threshold level of harmful exposure
22 required to cause cancer?

23 A. Yes.

24 Q. Doctor, in your opinion, there is asbestos
25 contamination in talcum powder products, and that

1 contamination intensifies, in your words, the
2 product's carcinogenic effect. Correct?

3 A. That's correct.

4 Q. You are not a mineralogist?

5 A. That's true.

6 Q. And you are not a geologist?

7 A. That's correct.

8 Q. Although you have awareness and training
9 regarding asbestos as it relates to occupational and
10 general environmental exposures, you do not hold
11 yourself out as an asbestos expert. True?

12 A. Outside of that context, no.

13 Q. Your opinion -- strike that.

14 You mean the context of the preface of my
15 question. Correct?

16 A. Outside of the context of human health effects,
17 no.

18 Q. Your opinion as a medical toxicologist
19 testifying to Her Honor is that any amount of asbestos
20 can cause ovarian cancer. Right?

21 A. Any amount of asbestos exposure to the ovary has
22 the potential to cause ovarian cancer.

23 Q. You agree that asbestos is found in the
24 environment. Right?

25 A. Yes.

1340

1 Q. Including in our air and drinking water?

2 A. Yes.

3 Q. As a matter of fact, IARC has stated that even
4 in rural locations, a typical concentration of
5 asbestos is 10 fibers per cubic meter. Right?

6 A. Yes.

7 Q. And in urban locations, typical concentrations
8 are tenfold higher. Right?

9 A. Yes.

10 Q. In indoor air, the concentration of asbestos
11 ranges between 30 and 6000 fibers per cubic meter.
12 True?

13 A. Possibly.

14 Q. Do you remember that as part of the IARC
15 monograph that you reviewed?

16 A. I don't remember that specific statement.

17 Q. Let's take a look.

18 I would ask you to look at Exhibit A 70 which
19 should be in your first binder, the IARC monograph.
20 I'll direct your attention to page 240.

21 A. Okay.

22 Q. My question is: Do you remember that in the
23 IARC monograph at page 240, the writers wrote:

24 "In indoor air, eg., in homes, schools and
25 other buildings, measured concentrations of asbestos

1341

1 are in the range of 30 to 6000 fibers per cubic
2 meter."

3 A. I see that.

4 Q. Based on these findings by IARC, a person could
5 inhale or ingest asbestos fibers from the air they
6 breathe. Right?

7 A. Yes.

8 Q. IARC also said the general population can be
9 exposed to asbestos in drinking water. Right?

10 A. Yes.

11 Q. And that concentration, that is, drinking water,
12 they said can range anywhere from less than 1 fiber
13 per milliliter to 10 to 300 million fibers per liter
14 or even higher. Right?

15 A. I don't recall that either. I think it's a
16 reasonable thing to state.

17 Q. Take a quick look at page 244 of the monograph
18 in front of you. It carries over to page 245. Does
19 looking at that refresh your memory that the numbers I
20 cited were stated by IARC in the monograph?

21 A. Yes.

22 Q. You did not attempt to compare the levels of
23 asbestos exposure that you believe result from
24 perineal application of cosmetic talc to the levels of
25 asbestos exposure that occur in our daily lives.

1 Correct?

2 A. That's correct.

3 Q. You've testified that you do not know whether
4 all talcum powder products that are on the market
5 contain asbestos. Right?

6 A. Correct.

7 Q. You've also testified that all talcum powder
8 products contain a certain amount of asbestos. You
9 said it both ways. Correct?

10 A. They all contain a certain amount of asbestosiform
11 fibers as discussed in the IARC documents.

12 Q. Is that what the IARC document says? Does it
13 say all talcum powder products contain asbestosiform
14 products? Can you point us to that?

15 A. That's what I said based on my research.

16 Q. That is not what the IARC monograph said. True?

17 A. I don't recall if the IARC monograph addressed
18 that.

19 Q. You have not attempted to quantify any alleged
20 contaminant including asbestos in Johnson & Johnson's
21 talcum powder products. Correct?

22 A. Correct.

23 Q. You defer to other experts plaintiffs hired for
24 that. Right?

25 A. Yes. I also used Johnson & Johnson's own

1 internal documents and those of its suppliers.

2 Q. I direct your attention to page 143 of your
3 deposition:

4 "QUESTION: Have you made any effort to
5 quantify the amount of any alleged contaminant in the
6 Johnson & Johnson Consumer talcum powder?

7 "ANSWER: That wasn't my charge. I defer to
8 the other experts in this case."

9 That was your testimony. Correct?

10 A. Correct.

11 Q. Do you know one way or the other whether any of
12 the experts plaintiffs' counsel has hired have
13 quantified the alleged contaminants in Johnson &
14 Johnson talcum powder products?

15 A. Yes. I think there has been an attempt to
16 quantify things like asbestos and fibers in Johnson &
17 Johnson powder products.

18 Q. You believe there has been some quantification
19 for purposes of this MDL proceeding of the amount of
20 the alleged contaminants in J&J talcum powder
21 products?

22 A. Yes.

23 Q. To be clear, your opinion that talcum powder
24 causes ovarian cancer is not dependent on talcum
25 powder products containing asbestos. Right?

1 A. That's correct.

2 Q. In other words, it would still be your opinion
3 that talcum powder causes ovarian cancer even if it
4 did not contain asbestos?

5 A. Yes, it would.

6 Q. You do not personally have expertise to
7 determine whether there is asbestos in J&J's talc
8 products. True?

9 A. Well, I could run the studies myself. I've done
10 that sort of thing before, but I haven't been asked to
11 and I have no plans to.

12 Q. You did not make any effort to investigate the
13 alternative explanations for the data -- strike that.

14 If the Johnson & Johnson company's scientists
15 and if Imerys' scientists, the suppliers' scientists
16 opined that tests do not actually show asbestos, you
17 have no expertise to dispute that; do you?

18 A. I think a statement to that effect is refuted by
19 Johnson & Johnson's own documents.

20 MR. WILLIAMS: Permission to read.

21 THE COURT: Yes.

22 Q. Page 150 of your deposition, line 22, through
23 page 151, line 6:

24 "If the Johnson & Johnson company --
25 companies' scientists and Imerys' scientists opined

1345

1 that those tests don't actually show asbestos, you
2 have no expertise to dispute that, do you?

3 "ANSWER: No, I don't have any personal
4 expertise to dispute that."

5 That was your testimony. Correct?

6 A. I'm sorry. What page are you on?

7 Q. 150, line 15. Actually, that question was on
8 page 150, line 22, to 152, line 6.

9 That was your testimony. Correct?

10 A. (No response.)

11 Q. Did I read that right?

12 A. Yes, you did.

13 Q. So if Dr. Longo is wrong, that is, if his
14 opinion fails to meet the Daubert standards according
15 to Her Honor, you have no scientific capability to
16 fill that gap. True?

17 A. Well, as I mentioned before, I do have the
18 capability, but this is not something I routinely do,
19 at least not anymore. Therefore, it would be
20 difficult for me to do that. But I'll reiterate that
21 there are other sources of information including the
22 Johnson & Johnson and Imerys internal documents.

23 Q. If Dr. Longo's analysts -- that is, the people
24 who work for Dr. Longo who actually conducted the
25 tests, if they applied their chosen methodologies in

1 an unreliable or incomplete or results-oriented
2 manner, that would affect your reliance on Dr. Longo's
3 litigation reports, true?

4 MS. O'DELL: I object to the question, your
5 Honor. Lack of foundation.

6 THE COURT: I think he's probably exploring if
7 in any way -- what he's really relying on. I'm permit
8 the question. No one has found anything yet of the
9 methods.

10 THE WITNESS: If Dr. Longo's report -- if I
11 was provided information that showed me that I could
12 not rely upon it, it would change certain of my
13 opinions, yes.

14 BY MR. WILLIAMS:

15 Q. If Dr. Longo's analysts's findings could not be
16 replicated by other scientists, that would affect your
17 reliance on Dr. Longo's litigation reports; would it
18 not?

19 A. It would depend on the specific findings.

20 Q. You are not a microscopist. True?

21 A. That's correct.

22 Q. Your opinion that talcum powder causes ovarian
23 cancer was formed based on research done on
24 commercially available talcum powder products?

25 A. In part.

1 Q. And you believe that -- strike that.

2 Do you believe that all talcum powder products
3 contain a small quantity of asbestos?

4 A. I think in the large sense, all talcum powder
5 products probably do or have contained a certain
6 amount of asbestos. That doesn't mean that I think
7 there is asbestos in every bottle of talcum powder.

8 Q. Now, with the first part of your answer to that
9 question, were you speculating?

10 A. No.

11 Q. The opinion that you just expressed is not based
12 on any experiment or study that you yourself have
13 done. Correct?

14 A. I have looked at analytical results of
15 quantities of talc obtained from various locations,
16 geologic deposits around the world for analysis and
17 research reports relating to others, and very many of
18 them report the occurrence of asbestos, and I am
19 hard-pressed to know any that don't.

20 MR. WILLIAMS: I move to strike that as
21 nonresponsive, your Honor.

22 THE COURT: Okay.

23 MR. WILLIAMS: Or I'll just ask another
24 question.

25 THE COURT: His question was any study or

1 experiment you have done. Do you want to answer that
2 question.

3 MR. WILLIAMS: I'll ask it again.

4 BY MR. WILLIAMS:

5 Q. The opinion that you have expressed, that all
6 talcum powder products contain asbestos, is an opinion
7 that is not based on any experiment that you yourself
8 have done?

9 A. That's correct.

10 Q. In other words, the effect of potential
11 contaminants, whatever they may be, on the
12 carcinogenicity of talcum powder is reflected in the
13 results of studies you relied upon to form your
14 opinions in this case?

15 A. That's true.

16 Q. The results of the talc studies that have been
17 reported in the papers that you have reviewed
18 necessarily reflects whatever potential contaminants
19 are contained in talc. Right?

20 A. Yes.

21 Q. For example, you have reviewed a number of
22 epidemiological studies relating to talcum powder
23 products and whether they are associated with ovarian
24 cancer. Correct?

25 A. That's correct.

1 Q. And whatever is contained in those talcum powder
2 products would be reflected in the results of those
3 studies. True?

4 A. That's correct.

5 Q. In connection with forming your opinion in this
6 case, you looked at epidemiologic studies concerning
7 asbestos exposure in addition to the studies relating
8 to talc exposure. Correct?

9 A. Yes.

10 Q. Those are two separate sets of studies. True?

11 A. For the most part they are.

12 Q. The asbestos studies that have statistically
13 significant findings for an association between
14 asbestos and ovarian cancer all involved heavy
15 occupational exposure to asbestos. True?

16 A. They do not. There are a number of studies that
17 involve domestic exposure or exposure to wives of
18 asbestos workers and that sort of thing.

19 Q. The ones that relate a statistically significant
20 association relate to heavy occupational exposure, do
21 they not?

22 A. Again, I'm not sure that's true.

23 Q. We'll check it out later perhaps.

24 None of the studies involving asbestos
25 exposure involved perineal application of talcum

1350

1 powder products. Right?

2 A. That was not a data point that was collected in
3 those studies.

4 Q. You do not know the dose of asbestos to which
5 the women in those occupational studies were exposed.
6 Right?

7 A. In some cases those doses were estimated based
8 on occupational activity and so forth.

9 Q. You do not have any information how the dose of
10 asbestos to which the women in those studies were
11 exposed during their occupational exposure compares to
12 any exposure to asbestos from the use of body powder.

13 Correct?

14 A. I think I could make a qualitative assessment of
15 the relative doses.

16 MR. WILLIAMS: Permission to read.

17 THE COURT: Yes.

18 Q. I'll direct your attention to page 298 of your
19 deposition, lines 2 through 14:

20 "QUESTION: And you don't have any information
21 how the dose of asbestos to which these women were
22 exposed during their heavy occupational exposure
23 compares to any exposure to asbestos from the use of
24 body powder. Correct?

25 "ANSWER: Well, I think these were not all

1351

1 occupational exposures, but I do not have information
2 regarding things like the route of exposure, no.

3 "QUESTION: Do you have any information
4 regarding the dose?

5 "ANSWER: No, I do not."

6 Doctor, you agree that exposure to asbestos
7 through perineal talc use is different from the heavy
8 occupational exposure to asbestos, that has been the
9 subject of research on asbestos and ovarian cancer.

10 True?

11 A. Well, of course it's different but it's still
12 asbestos.

13 Q. You would agree that it's different. Right?
14 Those two exposures are different. Right?

15 A. The exposures are different in terms of the
16 primary route of exposure and they're different in
17 terms of quantity. But it's still asbestos and in
18 that sense it's the same.

19 MR. WILLIAMS: Permission to read, your Honor.

20 THE COURT: Yes.

21 MR. WILLIAMS: Page 168, line 13, through 18.

22 Q. (Reading.)

23 "QUESTION: Would you agree that exposure to
24 asbestos through a perineal cosmetic talc use is
25 different from the heavy occupational exposure that

1 has been primarily researched?

2 "ANSWER: Yes I agree with that."

3 That was the entire answer to the question
4 that you gave. Correct, sir?

5 A. Yes, but I believe I extended that in the
6 questions here this morning.

7 Q. The question here this morning?

8 A. I guess it's this afternoon now.

9 THE COURT: He just meant here as opposed to
10 in your deposition.

11 THE WITNESS: Yes, here.

12 Q. You are not able to make any comparison between,
13 on the one hand, the amount of asbestos to which the
14 women in these occupational studies were exposed and,
15 on the other hand, the amount of asbestos to which any
16 woman who has used Johnson & Johnson's talcum powder
17 product was allegedly exposed. True?

18 A. I think, as I mentioned before, I can make a
19 qualitative assessment of the exposure level.

20 MR. WILLIAMS: Permission to read, your Honor.

21 THE COURT: Yes.

22 Q. Page 299 of your deposition, lines 1 through 9:

23 "QUESTION: Can you make any comparison
24 whatsoever to the amount of asbestos to which these
25 women were exposed to any exposure by any woman who

1353

1 has used a Johnson & Johnson body powder?

2 "ANSWER: I don't think I'm able to make that
3 kind of comparison."

4 That was the question you were asked and the
5 answer you gave at your deposition?

6 A. Yes.

7 MR. WILLIAMS: Your Honor, is this a good time
8 for the lunch break?

9 THE COURT: Sure. We'll take 45 minutes,
10 please.

11 THE DEPUTY CLERK: All rise.

12 (The luncheon recess is taken.)

13 (Continued on the next page.)

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A F T E R N O O N S E S S I O N

3 THE DEPUTY CLERK: All rise.

4 THE COURT: Thank you.

6 | ARCH CARSON, resumed.

8 CROSS-EXAMINATION (continued)

9 | BY MR. WILLIAMS:

11 Q. Dr. Carson, before the break there was a point
12 in time when I was asking you about the
13 epidemiological studies that related to asbestos. Do
14 you recall that?

15 A. Yes.

16 Q. And we had a discussion about how some of those
17 studies related to heavy occupational exposure and
18 others of those studies dealt with women and girls
19 with environmental exposure. Do you recall that?

20 A. Or domestic exposure, yes.

21 Q. Do you remember we had a back-and-forth about
22 whether the study relating to women and girls were
23 studies that failed to find a statistically
24 significant association, and you said you weren't sure
25 if that was true. Do you remember that?

1 A. That's correct.

2 Q. Let me direct your attention to your report
3 which is Tab C 9. I'll direct your attention to page
4 that paragraph in the middle of the page that refers
5 to the IARC working group and those environmental
6 studies, and it says:

7 "The IARC working group concluded that, quote,
8 a causal association between exposure to asbestos and
9 cancer of the ovary was clearly established based upon
10 five strongly positive cohort mortality studies of
11 women with heavy occupational exposure to asbestos."

12 And then it cites IARC. Correct?

13 A. That's correct.

14 Q. So the studies that correlate or find the
15 association between asbestos and ovarian cancer are
16 all studies that deal with heavy occupational
17 exposure. Right?

18 A. The studies that are significant?

19 Q. Yes.

20 A. I still can't tell you if that is true. I would
21 have to look at those studies again in order to be
22 able to agree with you.

23 Q. You said in your report:

24 "Studies showing that women and girls with
25 environmental but not occupational exposure to

1 asbestos had positive, though nonsignificant,
2 increases in both ovarian cancer incidence and
3 mortality."

4 And it cites 12 studies. Do you see that?

5 A. Yes, I think that's a quotation from the IARC
6 monograph.

7 Q. And you wrote, quoting the IARC monograph,
8 "Those studies had nonsignificant findings." Correct?

9 A. Those are IARC's words. I'm not sure if I
10 reviewed the same studies that were considered by IARC
11 or not.

12 Q. You quoted IARC's words in your report. Right?

13 A. I did.

14 Q. Thank you.

15 I would like to talk about the IARC monograph
16 for a moment, and I'm referring to the IARC monograph
17 on asbestos from 2012. Do you have that in mind?

18 A. Yes.

19 Q. Now, when IARC classifies substances into
20 groups, it does so by specifying the type of cancer to
21 which the classification applies. Right?

22 A. Yes, that's correct.

23 Q. So if IARC places a substance in Group 1, as it
24 did, for example, with benzene, it will not just say
25 this substance causes cancer. It describes the type

1 of cancer that is related. Correct?

2 A. In most cases that's correct.

3 Q. Let's look at what IARC says in its final
4 evaluation. This is Exhibit A 70. In your book it
5 would be in Volume 1.

6 MR. WILLIAMS: Your Honor, also Volume 1.

7 Q. This is the IARC monograph from 2012. Correct?

8 A. Yes.

9 Q. Let me direct your attention to page 309, and
10 specifically the right-hand column, top paragraph, it
11 says:

12 "There is sufficient evidence in humans for
13 the carcinogenicity of all forms of asbestos," quote,
14 and then it mentions the different types.

15 "Asbestos causes mesothelioma and cancer of
16 the lung, larynx and ovary."

17 Did I read that correctly?

18 A. You read that correctly.

19 Q. This is an example of how IARC associates a
20 substance, here asbestos, with certain types of
21 cancer, and the types of cancer here are cancer of the
22 lung, larynx and the ovaries as well as mesothelioma.
23 Correct?

24 A. Yes.

25 Q. Let me go to the third paragraph in this section

1 which says:

2 "There is sufficient evidence in humans for
3 the carcinogenicity of talc containing asbestiform
4 fibers. Talc containing asbestiform fibers causes
5 cancer of the lung and mesothelioma."

6 Did I read that right?

7 A. You did.

8 Q. IARC does not reference cancer of the ovaries
9 with respect to talc containing asbestiform fibers,
10 does it?

11 A. Not in this case, no.

12 Q. Not in this monograph. Correct?

13 A. That's correct. Although there is -- in other
14 parts of this monograph they do allude to that
15 potential relationship.

16 Q. This is the summary evaluation section we are in
17 right now. Correct?

18 A. I believe it is, yes.

19 Q. And it does not reference ovarian cancer?

20 A. It does not.

21 Q. The next paragraph says:

22 "There is inadequate evidence in experimental
23 animals for carcinogenicity of talc containing
24 asbestiform fibers."

25 Did I read that right?

1 A. Yes.

2 Q. Do you agree or disagree with that statement?

3 A. There is limited evidence supporting the
4 carcinogenicity of talc containing asbestosiform fibers
5 in animal studies, yes.

6 Q. Do you believe that evidence is inadequate in
7 experimental animals?

8 A. It was inadequate for IARC's purposes.

9 Q. And their purpose was to determine whether or
10 not there was a sufficient scientific basis to
11 determine the connection between the substance and
12 cancer. Right?

13 A. That's their overall purpose, but they have
14 specific procedures they follow along the way in order
15 to do that.

16 Q. Let me ask you some questions about heavy
17 metals.

18 Your opinion is the presence of what you
19 describe as carcinogenic metals in talcum powder adds
20 to the carcinogenic potency in talc. Correct?

21 A. That's correct.

22 Q. Is it true, Dr. Carson, that none of the heavy
23 metals you list in your report has been identified as
24 carcinogenic to the ovary by IARC?

25 A. That's true.

1 Q. You nonetheless identify nickel and chromium as
2 Group 1 human carcinogens in your report. Right?

3 A. That's correct.

4 Q. You are not aware of any studies showing that
5 exposure to nickel, chromium and cobalt combined with
6 talc increases the risk of ovarian cancer. True?

7 A. I'm not aware of studies that separate those
8 constituents in a coordinated study. But certainly
9 there is allusion to the effects of those metals on
10 the carcinogenic behavior of talc.

11 Q. Is the answer to my question, yes, you are not
12 aware of any studies showing that exposure to nickel,
13 chromium, and cobalt combined with talc increases the
14 risk of ovarian cancer?

15 A. Not specifically.

16 Q. The studies do not show that specifically.
17 Correct?

18 A. That's correct.

19 Q. You agree that in general metals can differ in
20 their toxicity and potential carcinogenicity based on
21 their form. Right?

22 A. Yes.

23 Q. You know metals including chromium, nickel, and
24 cobalt come in different forms known as valent states.
25 Correct?

1361

1 A. Yes.

2 Q. Doctor, you do not specifically know the forms
3 or valent state of chromium, nickel or cobalt that you
4 say have been detected in cosmetic talc. True?

5 A. It depends on where they are at the moment that
6 you test them.

7 The metals are bound to the talc crystal and
8 in that form they participate in electrochemical
9 surface reactions. When they are liberated from the
10 crystal in solutions they behave differently. Also,
11 in some cases causing macromolecular damage. But you
12 have to be very specific about the questions you ask
13 in regard to toxicity of those metals for me to be
14 able to answer.

15 Q. You are not, at least in this litigation,
16 expressing any opinion as to the valent state of
17 chromium that may be found in cosmetic talc. Correct?

18 A. I think it may be different in a sample of
19 cosmetic talc versus in a cell inside a woman's ovary.
20 I could render an opinion but I need to know that
21 information.

22 MR. WILLIAMS: Permission to read, your Honor.

23 THE COURT: Yes.

24 Q. Page 181, line 4, through 181, line 10:

25 "QUESTION: You are not, at least in this

1 litigation today expressing any opinion as to the
2 valent state of chromium that may be found in cosmetic
3 talc correct.

4 There is an objection.

5 "ANSWER: No, I'm not."

6 You would be speculating, would you not,
7 Dr. Carson, to conclude that whatever valent state of
8 chromium, nickel, or cobalt may be in cosmetic talc
9 are the type you say are carcinogenic. True?

10 A. No, I would not be speculating. They are of the
11 type that are carcinogenic.

12 Q. But you have not done the study of the valent
13 state. Correct?

14 A. The valent state is immaterial.

15 Q. Let me ask you some questions on dose as it
16 relates to heavy metal. You do not know the amount of
17 chromium, cobalt and nickel that are in talc
18 generally. True?

19 A. It varies considerably from batch to batch.

20 Q. But you don't know what that amount is?

21 A. No, I can't know it because it's variable.

22 Q. You do not know the amounts of either the heavy
23 metals or the fragrance chemicals in the talcum powder
24 at issue in this case. Correct?

25 A. Again, the fragrance chemicals are probably more

1 reliable in terms of their quantity, but I don't have
2 that information.

3 Q. The answer is you do not know the amount of
4 either the heavy metals or the fragrance chemicals in
5 the talcum powder for this case. Correct?

6 A. That's correct. But I know there is some there
7 of both.

8 Q. You have testified that those heavy metal
9 elements are included as impurities or in very small
10 quantities in some talc deposits and are present in
11 small amounts. Right?

12 A. Yes.

13 Q. The truth is, you are not an expert in talc
14 mining or mineralogy. True?

15 A. That's correct. I've observed those operations
16 but I'm not an expert.

17 Q. You do not know the steps involved in either the
18 mining of talc or the milling of talc. Right?

19 A. Yes, I do.

20 Q. The heavy metals chromium, cobalt, and nickel
21 are all naturally occurring minerals; are they not?

22 A. They are.

23 Q. They naturally occur in our body?

24 A. Yes, they do.

25 Q. They are present to some extent in food,

1 drinking water, bottled water and vitamins?

2 A. Also true.

3 Q. You have no idea how much of these metals, if
4 any, reaches a woman's ovaries when she uses talc.
5 True?

6 A. I think I can say that the amount that is
7 incorporated into the talc crystal reaches the ovaries
8 as the talc reaches the ovaries.

9 MR. WILLIAMS: Permission to read?

10 THE COURT: Yes.

11 Q. Page 169, lines 17 through 23?

12 "QUESTION: Do you have any idea how much of
13 these metals, if any, reaches a woman's ovaries each
14 time they use talc?

15 "ANSWER: I can't tell you how much, but I can
16 tell you that some does -- and it is -- it remains in
17 the talc until long after it reaches the ovaries."

18 Dr. Carson, you don't have any evidence that
19 the blood levels of these metals are any higher in
20 genital talc users as compared to non-users of talc.
21 Right?

22 A. I don't have any information to that effect, but
23 I can tell you I would not expect them to be
24 different.

25 Q. You do not have any evidence that the blood or

1365

1 tissue levels of any trace heavy metals are higher in
2 genital talc uses compared to non-users. True or not?
3 True?

4 A. Again, the point is immaterial, but I do not
5 have any reason to believe or any understanding they
6 are different.

7 Q. You made no effort to quantify the amount of
8 alleged heavy metal contaminants in J&J's talcum
9 powder products?

10 A. No, I didn't.

11 Q. You leave that job to other experts. Right?

12 A. Yes.

13 Q. Dr. Longo did not quantify the amount of heavy
14 metal contaminants in J&J's talcum powder products,
15 did he?

16 A. Not that I recall.

17 Q. Are you aware of any expert designated by the
18 plaintiffs in this litigation who has quantified the
19 amount of alleged heavy metal contaminants in J&J's
20 talcum powder?

21 A. I honestly can't recall where I saw all the
22 information that I received regarding content of those
23 metals in J&J's talcum powder.

24 Q. As you sit here today, you cannot list for us an
25 expert who undertook that analysis?

1 A. There are a number of experts, mostly defense
2 experts, who made statements regarding those things,
3 and there were internal documents of J&J and Imerys
4 that also addressed those in some cases.

5 Q. As you sit here, Doctor, you cannot tell us any
6 expert witness designated by the plaintiffs in this
7 litigation who has quantified the amount of heavy
8 metal contaminants in J&J's product. Right?

9 A. Right.

10 Q. You did not conduct an exposure assessment
11 specific to the alleged heavy metals contained in
12 talcum powder?

13 A. Well, I did do an exposure assessment in terms
14 of the metals remaining in the crystals long after
15 they reached the ovaries when that occurs.

16 MR. WILLIAMS: Permission to read, your Honor?

17 THE COURT: Yes.

18 Q. Page 175, lines 6 through 11?

19 "QUESTION: Did you look at any exposure
20 assessment specific to the alleged heavy metals
21 contained in talcum powder?

22 "ANSWER: No, I did not."

23 A. That's different from the question you asked me.
24 You asked me if I performed an exposure assessment.

25 Q. You did not perform an exposure assessment.

1 Correct?

2 A. Well, I did in terms of what I just told you,
3 that I determined that if talc makes it to the ovary,
4 the metal impurities contained in the crystals make it
5 there as well.

6 Q. You did not conduct a dose-response assessment
7 with respect to chromium, cobalt, nickel or any other
8 heavy metal?

9 A. No, I did not.

10 Q. In addition to your opinion regarding heavy
11 metals, it is your opinion that the fragrance
12 chemicals added to talc contribute to the carcinogenic
13 effects. Is that right?

14 A. Yes.

15 Q. But you don't know the amount of any fragrance
16 in J&J's talc products. Right?

17 A. Well, in a very crude way, there is information
18 from Dr. Crowley's report that can lead to conclusions
19 regarding that.

20 Q. At the time you rendered your opinions included
21 in your report you did not know or have any
22 understanding as to the amounts of fragrance chemicals
23 that are in talcum powder. Right?

24 A. I had seen information regarding it, and I had
25 seen that fragrance chemicals were added to a level as

1 great as 1 percent by weight, but I don't recall
2 having any more specific information than that.

3 MR. WILLIAMS: Permission to read, your Honor?

4 THE COURT: Yes.

5 Q. Page 73, lines 15 through 20:

6 "QUESTION: Do you know or have any
7 understanding as to the amounts of fragrance chemicals
8 that are in the talcum powder?

9 "ANSWER: I do not have the specific
10 formulation or quantities of those substances that
11 contributed to the products."

12 Dr. Carson, you have not done any analysis to
13 consider dose, frequency, duration, or time of
14 exposure as it relates to the fragrance ingredients
15 that you contend are somehow biologically relevant to
16 ovarian cancer. True?

17 A. Well, regarding frequency and quantity, they
18 would be based on the amount of talcum powder use,
19 frequency and quantity.

20 Q. What information did you rely upon or use, if
21 any, to make a dose-response assessment with respect
22 to any fragrance chemicals?

23 A. Only the information that was present in Dr.
24 Crowley's report.

25 MR. WILLIAMS: Permission to read?

1 THE COURT: Yes.

2 Q. Page 174, lines 3 through 10:

3 "QUESTION: What information did you rely upon
4 or use, if any, to make a dose-response assessment
5 with respect to any fragrance chemicals?

6 "ANSWER: There is no information available to
7 do a dose-response estimate for the fragrances."

8 I would like to quickly jump to the topic of
9 inhalation as a theory for you. Do you believe
10 inhalation is likely -- I believe you called it a
11 secondary route of exposure of talcum powder to the
12 ovaries. Right?

13 A. Yes.

14 Q. You do not cite any studies in the body of your
15 report showing that inhaled talc reaches the ovaries.
16 Correct?

17 A. That's correct.

18 Q. You have done no research yourself on whether
19 inhaled talc can migrate to the ovaries. Right?

20 A. That's correct. Several of the authors that I
21 did cite in my report alluded to the possibility of
22 inhalation being a secondary route of talc exposure to
23 the ovaries, but there was no quantitation or research
24 regarding that.

25 Q. One of the documents that you reviewed in your

1370

1 work here was the 2010 IARC monograph. Right?

2 A. Yes.

3 Q. And you are aware of the fact the IARC monograph
4 concluded there is insufficient evidence of
5 carcinogenicity of talcum powder that enters the body
6 by the route of inhalation. Correct?

7 A. Yes.

8 Q. Let me ask you about the structure of your
9 report itself.

10 THE COURT: Just to follow up on this: Based
11 upon the testimony you just gave, you said you didn't
12 cite to any study showing the connection between
13 inhalation and reaching the ovary?

14 THE WITNESS: Other than the IARC monograph
15 itself.

16 THE COURT: Which said that was not
17 sufficient. So what's the basis for your opinion as a
18 secondary source?

19 THE WITNESS: I have been working in that area
20 for all of my professional life. We know if you
21 inhale dust or fibers, parts of it makes it into the
22 bloodstream and may circulate to many places around
23 the body.

24 THE COURT: Specifically the ovaries?

25 THE WITNESS: Specifically the ovaries

1 included.

2 THE COURT: How do you know that, that
3 specific connection?

4 THE WITNESS: A number of the articles I do
5 cite indicate talc has been found in ovaries of women
6 who have never used talcum powder, and there is
7 multiple speculation those articles regarding the
8 source of that talc and where it came from, and
9 inhalation is one of those proposed mechanisms.

10 THE COURT: Those are things you are throwing
11 out as possibilities, but nothing that you could
12 testify to, to a reasonable degree of certainty; could
13 you?

14 THE WITNESS: I can testify to a reasonable
15 degree of certainty if talc is inhaled, some of it may
16 reach the ovaries.

17 THE COURT: Go ahead, Mr. Williams.

18 BY MR. WILLIAMS:

19 Q. One of the studies that I think you just
20 referred to was a study -- was the Heller 1996 study.
21 Correct?

22 A. Yes.

23 Q. That's the study that found talc in the ovaries
24 of women, some of whom used talc and some who never
25 used talc. Correct?

1 A. That's correct.

2 Q. Now, the authors of that study examined the
3 ovaries of 24 women undergoing oophorectomies.

4 Correct?

5 A. Correct.

6 Q. That's the procedure to remove one or both of
7 the ovaries?

8 A. That's correct.

9 MS. O'DELL: If Mr. Williams is going to ask
10 specific questions on those studies, I would ask that
11 Dr. Carson has it in front of him.

12 Q. It's Exhibit A 60, and that should be in your
13 first book.

14 MR. WILLIAMS: And yours as well, your Honor.

15 (Pause.)

16 Q. I would like to direct your attention to Table 3
17 on page 3 of Exhibit A 60. We'll put it up on the
18 board as well and blow it up. It's page 3.

19 12 women in the study reported talc use and 12
20 controls reported no use. That's in the left-hand
21 column. Right?

22 A. Yes.

23 Q. The authors found talc in the ovaries of all 24
24 patients regardless of whether they used talc or not.
25 Right?

1 A. That's correct.

2 Q. The authors concluded -- and this is page 5,
3 left-hand column, first sentence:

4 "The quantity of study detected in the study
5 did not correlate well with the reported exposure."

6 Right?

7 A. Yes.

8 Q. If we could, let's go to page 3 of Exhibit A 60,
9 the second column right above the comments. The study
10 authors stated there:

11 "There was no evidence of response to talc
12 such as foreign body, giant cell reactions or fibrosis
13 in the tissue."

14 Did I read that right?

15 A. Yes.

16 Q. This study, Heller 1996, did not note any
17 inflammation present in the ovaries with respect to
18 talc particles.

19 True?

20 A. That's correct.

21 Q. Let's go back to your litigation report. The
22 body of your report where you describe your opinions
23 and the studies and the other materials you relied
24 upon, and your analysis of those materials spans a
25 total of 10 1/2 pages. Is that true?

1 A. It is.

2 Q. Your specific conclusions and opinions are
3 expressed in Section 9 of your report. Right?

4 MR. WILLIAMS: Exhibit C 9 for the record.

5 Q. Do you see that section?

6 A. I'm having trouble finding my report.

7 Q. It should be in Volume 1. The C exhibits are
8 near the back.

9 A. I see it.

10 Q. Your conclusions in the opinion section begins
11 in the middle of page 7 and it goes over to the middle
12 of page 11. Right?

13 A. Yes.

14 Q. That section is 4 pages total. True?

15 A. Correct.

16 Q. Now, in preparing your report, you reviewed all
17 of the literature listed in Exhibit B, and that begins
18 on page 25 of the report. Is that right?

19 A. Yes.

20 Q. I'll represent to you that there are 300
21 publications, over 300 that you list in that section.

22 Now, you cite some of the literature cited in
23 Exhibit B in the body of your report. Right?

24 A. Yes.

25 Q. The materials you specifically cite are

1 identified in the references that follow the body of
2 your report beginning on page 11. Correct?

3 A. That's correct.

4 Q. That is a subset of the others. True?

5 A. Yes, it is.

6 Q. You do not state in your report how you weighted
7 the different publications you considered in reaching
8 your opinions. That was not described in your report.
9 True?

10 A. Yes, I agree it was not.

11 Q. And you do not describe why some studies were
12 important in forming your opinions and others were
13 not. True?

14 A. That's true.

15 Q. One of the factors to which you gave significant
16 weight in reaching your opinions in the litigation was
17 biologic plausibility, also known as biologic
18 mechanism. Correct?

19 A. That's correct.

20 Q. Essentially, if no rational presentation of
21 mechanisms can be proposed, you believe causation is
22 less likely?

23 A. I think you are closer to causation if you can
24 show a credible biological mechanism that links the
25 exposure and the disease.

1 Q. And there are two parts to your analysis of
2 biological plausibility. First you say portions of
3 the talcum powder applied perineally are transferred
4 into the female reproductive tract, and some makes it
5 all the way to the ovaries. That's part 1. Correct?

6 A. Yes.

7 Q. Part 2 you say is that talc produces chronic
8 inflammation in the epithelial tissue of the ovaries
9 and surrounding epithelial tissues. Right?

10 A. Yes.

11 Q. This two-step process was the subject of one of
12 the slides that Ms. O'Dell and you went over earlier
13 today?

14 A. That's correct.

15 Q. Before we dive into your theory regarding
16 biological mechanism, let me ask you a few things
17 about the area of your expertise.

18 You do not treat woman for gynecologic cancer.
19 True?

20 A. That's true. I no longer do that.

21 Q. You have never treated any patients for ovarian
22 cancer?

23 A. I have in the context of medical training.

24 MR. WILLIAMS: Permission to read, your Honor?

25 THE COURT: Yes.

1 Q. Pages 349, line 23, to 350, line 3:

2 "QUESTION: You testified earlier that you
3 have not treated any patients with ovarian cancer. Is
4 that correct?

5 "ANSWER: Not knowingly, not because of
6 ovarian cancer."

7 A. Not as an attending physician.

8 Q. You are neither a gynecologist nor an
9 oncologist. Right?

10 A. That's correct.

11 Q. You have never had a patient referred to you to
12 determine why they have ovarian cancer. Correct?

13 A. Not specifically, no.

14 Q. You are not a pathologist?

15 A. No, I'm not.

16 Q. You are not a cancer biologist?

17 A. Well, I consult with a cancer hospital regarding
18 biological mechanism issues.

19 MR. WILLIAMS: Permission to read, your Honor?

20 THE COURT: Yes.

21 Q. Page 60, lines 21 to 24:

22 "QUESTION: You are not a cancer biologist?

23 "ANSWER: That's correct."

24 Doctor, you are not an expert in the
25 phenomenon of oxidative stress. Correct?

1 A. Oxidative stress comes around in very many forms
2 in a lot of things that I get professionally involved
3 in as an expert. So it's hard to draw the line
4 between expertise and ancillary activities.

5 Q. But you would not call yourself a specific
6 expert in oxidative stress. True?

7 A. I don't put myself out as the expert in
8 oxidative stress, no.

9 Q. Let's start with the inflammation portion of
10 your theory.

11 At the time you formed your opinions in this
12 case you were not aware of any study on humans showing
13 that externally applied talcum powder causes any
14 biologic response including inflammation anywhere in
15 the reproductive tract. Right?

16 A. Well, I believe that the studies that I have
17 cited on migration and the studies I cited on talc
18 inflammation taken together really address that
19 question. So I was aware of that information and able
20 to draw conclusions regarding it.

21 MR. WILLIAMS: Permission to read?

22 THE COURT: Yes.

23 Q. Page 322, lines 3 through 23:

24 "QUESTION: And I know we have been through
25 this already, but to your knowledge there are no

1 studies reporting biologic responses to talc in the
2 vagina. Correct?

3 "ANSWER: Not that I'm aware.

4 "QUESTION: You are not aware of any studies
5 reporting biologic responses to talc in the cervix.
6 Correct?

7 "ANSWER: Correct.

8 "QUESTION: Are you aware of any study
9 reporting biologic response to the uterus?

10 "ANSWER: No.

11 "QUESTION: Are you aware of any studies
12 reporting a biologic response in the fallopian tubes?

13 "ANSWER: Well, I don't -- I'm not aware of
14 studies that draw a direct correlation between
15 exposure to talc and reaction in the fallopian tubes."

16 Q. I would like to ask you some questions regarding
17 animal studies and specifically the connection between
18 the animal studies and your theory talc causes
19 inflammation which in turn causes cancer.

20 Do you have that topic in mind?

21 A. Yes.

22 Q. Let's take a look at what you cite in your
23 report in support of your opinion on animal studies,
24 and that's Exhibit C 9, and I would like to direct
25 your attention to page 4.

1380

1 On page 4, in the middle of the page there is
2 a heading "Talcum Powder and Cancer." Do you see
3 that?

4 A. Yes.

5 Q. And the second line there says:

6 {Talc has caused cancer when implanted in
7 various tissues and under the skin in laboratory
8 animals. It causes inflammation and fibrotic reaction
9 including the chemotaxis of inflammatory immune cells
10 and accelerated growth and division of cells in the
11 involved tissues.}

12 And you cite Okada 2007. Right?

13 A. Yes.

14 Q. And that that causes inflammation -- in the
15 second sentence there is a reference to talc in your
16 report. Right?

17 A. That's correct.

18 Q. You cite one and only one study for that
19 proposition, Okada 2007?

20 A. That's one that I put there, yes.

21 Q. It's the only one you cited. Right?

22 A. At that location, yes.

23 Q. Now, Okada was not looking at talc at all.
24 Correct?

25 A. I think that may be the case. I would have to

1 refresh my memory.

2 MR. WILLIAMS: Permission to read.

3 THE COURT: Yes.

4 Q. Page 287 of Dr. Carson's deposition, line 22,
5 through 288, line 1:

6 "QUESTION: Okay. And yet Okada, the study
7 that you cite for that proposition, doesn't look at
8 talc at all, does it?

9 "ANSWER: No."

10 Now, Okada does not say anything about ovarian
11 cancer. Is that correct?

12 A. That's correct. It's a study involving foreign
13 body-induced carcinogenesis.

14 Q. Let's take a look at the study. It is in your
15 book. It should be in Volume 2, Dr. Carson. It's
16 Exhibit P-256.

17 MR. WILLIAMS: Your Honor, that would be in
18 your book No. 4.

19 Q. Do you have it in front of you?

20 A. I do.

21 Q. Please turn to page 3 of the exhibit. I'll
22 direct your attention to the left-hand column, middle
23 of the first full paragraph. That sentence reads,
24 quote --

25 MS. O'DELL: Did you say 256?

1 MR. WILLIAMS: P-256.

2 Q. Dr. Carson, the sentence that's on the board
3 reads:

4 "Brand, et al, verifies that carcinogenic
5 potential depended on the properties of foreign body,
6 such as shape/size, smoothness, hardness, porosity and
7 electrostatic load."

8 Did I read that correctly?

9 A. Yes.

10 Q. In other words, not all foreign bodies have the
11 same capacity to be carcinogenic. Is that a true
12 statement?

13 A. Yes.

14 Q. Okada has a heading for particulate carcinogens,
15 and it lists them on the very first page of the study.
16 Do you remember that?

17 A. (No response.)

18 Q. Here on the first page, right-hand column, under
19 "particulate carcinogens" --

20 A. I see it.

21 Q. It says:

22 "Particulate carcinogens are" and then it
23 gives a long list. Do you see that?

24 A. Yes.

25 Q. Talc is not on there, right?

1 A. I don't believe it is.

2 Q. Let's look at another study.

3 I would like to direct your attention to the
4 Radic study from 1988. You cite the Radic 1988 study
5 as an animal study that supports your opinion that
6 talc causes ovarian cancer. I'll refer you to where
7 you do that. It's in page 5 of your report, the top
8 of the page. Do you see that?

9 A. Yes.

10 Q. Take a look at what we just pulled out, P-264,
11 the 1988 study entitled Immunosuppression Induced by
12 Talc Granulomatosis in the Rat.

13 Talc granulomatosis is a disease of the lung.
14 Is that right?

15 A. In most cases that's correct, but it can be
16 present in other parts of the body as well.

17 Q. In Radic 1988 the authors injected one full gram
18 of talc into rats at four subcutaneous injection
19 sights in the backs of the animals. Right?

20 A. Yes.

21 Q. This study did not involve ovarian tissue.
22 Correct?

23 A. Not directly, yes.

24 Q. The authors were not looking at the rats'
25 ovaries. True?

1 A. That's correct.

2 Q. The authors reported talc injections cause
3 granulomatosis in the rats. Correct?

4 A. Yes.

5 Q. Granulomatosis is not cancer. True?

6 A. That's correct. It's an immune inflammatory
7 reaction.

8 Q. Do you agree that there is no good science, no
9 good scientific basis today for the opinion granulomas
10 cause ovarian cancer?

11 A. I don't know of anyone who holds that opinion.

12 Q. And that's because you do not think they cause
13 granulomas and ovarian cancer?

14 A. I don't believe granulomas specifically cause
15 ovarian cancer. The inflammation associated with them
16 may.

17 Q. Granulomas do not cause ovarian cancer. That is
18 your scientific belief. Correct?

19 A. Yes.

20 Q. The authors of Radic 1998 found that the rats
21 immune response was suppressed by talcum powder.
22 Right?

23 A. Yes, I believe they did.

24 Q. Immunosuppression refers to the suppression of
25 the body's immune system and its ability to fight

1 infections and other diseases. Right?

2 A. Yes.

3 Q. Immunosuppression and cancer are not one and the
4 same. True?

5 A. That's correct.

6 Q. The Radic study did not find neoplastic changes
7 in the rats. Correct?

8 A. Not that I recall.

9 Q. And the word "cancer" does not appear anywhere
10 in that study. True?

11 A. Not that I recall.

12 Q. One of the studies you cited earlier today was
13 an animal study called Hamilton. Do you remember
14 that?

15 A. Yes.

16 Q. Take a look at that study. It is found in your
17 first notebook. It is Exhibit A 53.

18 Do you have the Hamilton study in front of
19 you, Doctor?

20 A. I do.

21 Q. You recognize that as the study by T.C.
22 Hamilton that you have been referencing earlier today?

23 A. Yes.

24 Q. In this study the authors surgically injected
25 talcum powder into the ovarian bursal sac of rats.

1 Right?

2 A. That's correct.

3 Q. Out of the 10 rats injected with talc, four of
4 them, less than half, showed some kind of papillary
5 change in the ovarian surface epithelium. Correct?

6 A. That's correct.

7 Q. The authors concluded that the epithelium
8 covering the papillary areas was regular with no
9 evidence of cytoplasmic or nuclear atypia. Correct?

10 A. Correct.

11 Q. You see that in the abstract. Right?

12 A. Yes.

13 Q. Any atypia refers to nuclear abnormalities.
14 Correct?

15 A. That's correct.

16 Q. Now, please turn to page 4 of Exhibit A 53 and
17 look at the right-hand column last full paragraph.

18 MR. WILLIAMS: I don't think that's the part
19 that I wanted.

20 Q. There is a portion that says -- here it is. The
21 last full paragraph in the right-hand column. It
22 says:

23 "No evidence of cellular atypia or mitotic
24 activity was seen in the nonpapillary areas of the
25 surface epithelium of the injected ovaries and in no

1 ovary was there any evidence of frank neoplasia."

2 Is that what that says?

3 A. Yes.

4 Q. Frank neoplasia is cancer. Correct?

5 A. It's precancer.

6 Q. What this was saying is there was no evidence of
7 precancer. Right?

8 A. Correct.

9 Q. To summarize this study, the chronic
10 inflammation seen in the rats in the Hamilton study
11 did not lead to neoplastic changes or cancer.
12 Correct?

13 A. In these rat ovaries, correct.

14 Q. And the Hamilton study did not conclude that
15 chronic inflammation from talc led to neoplastic
16 changes or cancer. Right?

17 A. Correct.

18 Q. The immune responses reported in Hamilton were
19 not responses that led to the development of ovarian
20 cancer. True?

21 A. Apparently not. But the authors also go further
22 to discuss the differences between rats and humans in
23 interpreting these findings.

24 Q. Now, you talked earlier today when Ms. O'Dell
25 was speaking with you about papillary changes, and she

1 put up a slide that referred to the study commenting
2 on papillary changes. Do you recall that?

3 A. Yes.

4 Q. Do you remember whether the study attributed the
5 development of those papillary changes to talc?

6 A. I believe it did.

7 Q. Let's take a look. Page 6 of Exhibit A 53, the
8 first full paragraph in the right-hand column before
9 the acknowledgements says:

10 "It is clearly attempting to attribute the
11 papillary change in the surface epithelium of injected
12 ovaries to the direct effects of exposure to talc,
13 but an alternative explanation has to be considered."

14 And it goes on. Do you see that?

15 A. Yes.

16 Q. Is it important to consider alternative
17 explanations before attributing a specific response to
18 a specific exposure?

19 A. Of course.

20 Q. If we skip a sentence and go down, it says:

21 "Steroid hormone receptors have recently also
22 been reported as present in the rat ovarian surface
23 epithelium grown in vitro, and it is therefore
24 possible the changes seen in the surface epithelium of
25 the injected rat ovaries were the result of long-term

1 rather than intermittent exposure to the high
2 concentration of steroid hormones present in the
3 entrapped follicular fluid within the distended
4 bursa."

5 Doctor, as a result of the testing being done,
6 the injected rats would have been exposed long-term to
7 high concentrations of steroid hormones. Right?

8 A. Possibly.

9 Q. And long-term exposure to a high concentration
10 of steroid hormones is a legitimate alternative
11 explanation for the papillary changes in the four
12 rats. True?

13 A. That's true. The authors themselves summarized
14 this issue by saying in the sentences following where
15 you completed your excerpt:

16 "Hopefully, future studies will clarify
17 whether one or both of these possibilities has
18 relevance to the malignant process in the ovarian
19 surface epithelium."

20 Q. One of the studies that you cited earlier today
21 is the Keskin study from 2009. You are familiar with
22 that study?

23 A. Yes.

24 Q. That was one of the studies that formed the
25 basis of your opinions?

1 A. It was one I considered in arriving at my
2 opinions.

3 Q. The Keskin study is an example of a study
4 showing that talc causes chronic inflammation, and you
5 say that this is a study that shows chronic
6 inflammation that can lead to neoplastic change or
7 cancer. Right? That's how you cite it?

8 A. In my report?

9 Q. Let me ask you: Is this a study that you
10 believe is citable for the proposition that talc
11 causes chronic inflammation which leads to neoplastic
12 change or cancer in animals?

13 A. I cited this study and referred to it in my
14 presentation earlier this morning because I believe it
15 relates directly to inflammation in animals.

16 Q. And you do not cite it, I take it from your
17 answer just now, for the proposition that talc causes
18 chronic inflammation leading to neoplastic changes?

19 A. I think the study supports the chronic
20 inflammation. It doesn't necessarily support the
21 neoplastic change portion of your question.

22 Q. Lots of things cause inflammation. Right?

23 A. That's correct.

24 Q. Let's take a look at this study. It's Exhibit A
25 85. I would like to direct you to the findings. It's

1 page 2, right-hand column, paragraph 2, under
2 findings.

3 "In both the groups exposed to talc, Groups
4 III and IV, evidence of foreign body reaction and
5 infection along with an increase in inflammatory cells
6 were observed in all of the genital tissues."

7 Correct?

8 A. Yes.

9 Q. On the same page, page 2, you see where it says
10 "conclusions" down there at the bottom?

11 A. Yes.

12 Q. The conclusion says:

13 "Talc has unfavorable effects on the female
14 genital system. However, this effect is in the form
15 of foreign body reaction and infection rather than
16 neoplastic."

17 Did I read that right?

18 A. Yes.

19 Q. The authors drew a distinction between foreign
20 body reaction on the one hand and neoplastic change on
21 the other. Right?

22 A. Yes. I think that's how I characterized the
23 study a moment ago.

24 Q. The study did not report any neoplastic changes.
25 Correct?

1 A. Correct.

2 Q. The study also does not report any ovarian
3 cancer in any of the rats. Correct?

4 A. That's correct.

5 Q. And one of the studies or papers that you
6 referred to today is the Ness and Cottreau. It's from
7 1999, and that's Exhibit A 105 in your first book.

8 First of all, this Ness paper, this is a
9 review article?

10 A. That's correct.

11 Q. It is not presenting primary evidence or data.
12 Correct?

13 A. It's not a research study report, but it is
14 discussing data reported in others.

15 Q. And what this paper does is it lays out a theory
16 of inflammation. Right?

17 A. That's correct.

18 Q. What it does, it proposes what the authors
19 called a novel hypothesis. Correct?

20 A. At this point in time, I'm not sure I would
21 agree it was a novel hypothesis, but I think the
22 authors considered that would be a good way to present
23 it.

24 Q. Let's take a look at Exhibit A 105, page 2, the
25 second sentence of the abstract says:

1 "This paper reviews the epidemiologic
2 literature in the English language on risk factors and
3 protective factors for ovarian cancer and proposes a
4 novel hypothesis that a common mechanism underlying
5 this disease is inflammation."

6 Correct?

7 A. That's correct.

8 Q. They call it a "novel hypothesis." Right?

9 A. Yes.

10 Q. Drs. Ness and Cottreau do not in this paper
11 prove that inflammation causes ovarian cancer.

12 Correct?

13 A. That wasn't the purpose of this paper.

14 Q. The purpose of the paper --

15 A. The purpose of the paper was to discuss the
16 evidence to that point that they felt supported that
17 hypothesis.

18 Q. And the paper does not purport to provide any
19 data that establishes the accuracy of the hypothesis.

20 Correct?

21 A. It does discuss alternative explanations to some
22 extent and talks about strengths and weaknesses of
23 various studies that are included in the review.

24 Q. Take a look at page 4, the right-hand column,
25 midway down, it says:

1 "The link between talc exposure and ovarian
2 cancer is limited by a lack of supportive animal data
3 and an inconsistency in the detection of talc in the
4 ovarian tissue of women who reported heavy use."

5 Correct?

6 A. It took me a while to catch up with you. Let me
7 just read that.

8 Q. Sure.

9 (Pause.)

10 A. Yes, that's correct.

11 Q. The paper acknowledges on page 4 that the
12 dose-response evidence is inconsistent. Same
13 paragraph midway down?

14 A. Yes, it says that, but it also says -- it also
15 is, of course, just reviewing the epidemiologic data
16 up until the time of this paper, which was about 1998,
17 and it talks about the strength of the evidence, the
18 epidemiological evidence linking talc exposure through
19 perineal application and ovarian cancer.

20 Q. Let me ask you about one of the studies that
21 relates to one of the animal studies relating to the
22 impact of talc on ovaries in animals.

23 Let me have you look at the Boorman -- that is
24 Carson Exhibit 508. That would be in your second
25 binder.

1 MR. WILLIAMS: And, your Honor, that would be
2 in your third binder.

3 Q. Do you also have your report handy, Dr. Carson?

4 A. Not particularly handy.

5 Q. Let me put it up on the screen. I'm just going
6 to show you the references to this article in your
7 report. Your report is Exhibit C 9, and on pages 29
8 to 30, do you see you cited this Boorman study?

9 A. Yes.

10 Q. So let's go back to Boorman.

11 Now, this is a study that although you have it
12 in the back of your report as a reference, this is not
13 a study that you cited in the list of references in
14 your report. True?

15 A. That's correct.

16 Q. You do not address it in the body of the
17 litigation report. Right?

18 A. I didn't think it was fundamental to the
19 development of my opinions.

20 Q. Please turn to page 1, paragraph 2, of Exhibit
21 Carson 508. It lists over there the exposure and how
22 long the talc exposure lasted; does it not?

23 A. Yes.

24 Q. And, essentially, this is the entire lifetime of
25 a rat? The talc exposure lasted two years for the

1 lifetime of the rats?

2 A. The lifetime of the rats and two years in mice.

3 Q. The authors state:

4 "There were no exposure-related lesions in the
5 ovaries of rats, Table 1, or mice, Table II. However,
6 because of a concern of potential effects of talc on
7 the ovary, additional studies were performed."

8 Do you see that?

9 A. Yes.

10 Q. The studies examine lung and ovarian tissue from
11 10 female rats. Right?

12 A. Yes.

13 Q. Now, you understand Dr. Boorman and his
14 co-authors were doing additional testing of the same
15 ovaries taken from female rats as part of the 1993 NTP
16 study. Correct?

17 A. Yes.

18 Q. And you know the NTP study is one of the studies
19 upon which plaintiffs rely in this matter relating to
20 some bad effects of talcum powder. Correct?

21 A. Correct.

22 Q. That NTP study talks about rats who were exposed
23 weeks on end, 8 hours a day, to talcum powder, ended
24 up having some lung problems. Do you recall that?

25 A. Yes.

1 Q. You understand this Boorman study was a
2 follow-up to the NTP study where they took the same
3 rats, removed their ovaries, and took a look at them.
4 Right?

5 A. Correct.

6 Q. No talc was found in the rat ovaries. Correct?

7 A. Correct.

8 Q. This is page 1, over in the right-hand column,
9 the carry-over paragraph, last sentence:

10 "There was no material consistent with talc
11 found in the ovaries or ovarian bursa from any rats
12 from any group."

13 Right?

14 A. That's correct. I should point out this is an
15 inhalation study, and so that would be essentially the
16 sole route of exposure for talc.

17 Q. The study did not report any chronic
18 inflammation from the talc. Is that true?

19 A. It did report chronic inflammatory changes in
20 the respiratory systems.

21 Q. Did it report any incidence of ovarian cancer in
22 the rats?

23 A. No.

24 Q. Can we agree Boorman 1995 does not in fact show
25 that talc causes chronic inflammation leading to

1 neoplastic change?

2 A. It doesn't show that, but it doesn't rule it
3 out.

4 Q. Ms. Popkin would like me to read the last
5 paragraph. The last paragraph before the references
6 says:

7 "This would suggest extensive lifetime
8 exposure to talc does not result in the deposition of
9 talc in the ovary. Since the animals were exposed for
10 six hours per day with talc covering the fur and the
11 cage bars, there was ample opportunity for perineal as
12 well as oral and respiratory exposure. In the
13 extrapolation of these data one should consider
14 limitations relative to the marked anatomical and
15 physiological differences between rodents and humans."

16 Did I read that correctly?

17 A. Yes. This paragraph points out the authors were
18 concerned about the consideration of the differences
19 between humans and rats in interpreting issues like
20 migration from perineal exposure.

21 Q. This is a study that you did not feel should
22 make the cut in terms of being cited in your report.
23 Correct?

24 A. It didn't influence my opinions. So I didn't
25 cite it.

1 Q. Well, let me ask you some questions about
2 biological plausibility.

3 I would like to focus on -- let me check that.

4 Let me ask you about migration. There have
5 been no studies in women showing that talc applied to
6 the peritoneum not instilled into the vagina but
7 applied externally into the perineum manages to
8 migrate to the ovaries or the fallopian tubes?

9 A. I think the studies that utilize vaginal
10 installation are tantamount to perineal exposure
11 because the channel is an open channel between the
12 outside and the inside.

13 Q. What is the perineum?

14 A. It is the space between the anus and the pubic
15 bone.

16 Q. You have actually opined in this matter that the
17 external application of perineal talc outside of the
18 body in the perineal area is the same as internal
19 application in the reproductive tract. Is that true?

20 A. I think it is.

21 Q. Now, you draw no distinction between application
22 of perineal talc outside of the body and the injection
23 of talc inside the genital area. True?

24 A. I think there is an obvious distinction of where
25 quantities are deposited. Beyond that, after that,

1400

1 it's pretty much the same.

2 Q. You say "pretty much the same." Have you
3 studied the matter?

4 A. Casually.

5 Q. Do you think these proceedings are casual?

6 A. No, I don't.

7 Q. Now, that opinion that you just expressed is not
8 a gynecological opinion because you are not a
9 gynecologist. Right?

10 A. It is an opinion that's expressed in a number of
11 gynecological textbooks and writings on the subject.

12 Q. So a number of gynecological textbooks and
13 writings on the subject opine as you do that external
14 application of particles -- here, talcum powder -- is
15 the same as injecting talcum powder into the vagina.
16 Is that your testimony?

17 A. I don't think the references I was referring to
18 talk about talcum powder or injection of substances,
19 but they indicate it's an open channel, and the inside
20 and the outside are pretty much the same.

21 Q. That opinion that you just gave, that the area
22 of the human anatomy of a woman is an open channel, as
23 you say, is something we could find in textbooks?

24 A. Yes.

25 Q. Can you cite one?

1 A. Not right off hand.

2 Q. The ovaries are higher in the body relative to
3 the vagina. True?

4 A. You mean in terms of elevation?

5 Q. Higher up in the body than the vagina?

6 A. Yes. Of course it depends on the position of
7 the woman.

8 Q. If the woman were upside down, then the vagina
9 would be higher in the body. Right?

10 A. At least a portion of it, yes.

11 Q. If the woman were standing right-side-up or
12 sitting, the vagina would be lower. Right?

13 A. Probably, yes.

14 Q. Now, talc particles do not have motility in the
15 same way that sperm do. True?

16 A. That's correct.

17 Q. You agree with me that if talcum powder somehow
18 migrates from the perineal region to the ovaries,
19 exposure to talcum powder would be far greater in
20 concentration -- meaning there would be more talc in
21 the rectal area, the vulvar area, the vaginal area,
22 and so on. Correct?

23 A. It depends on the application of talc to that
24 area, and it also depends on things like whether or
25 not the woman bathes regularly, other hygienic

1 practices and activities.

2 Q. Page 198, lines 8 through 17?

3 "QUESTION: All right. If talcum powder
4 migrates from the perineal region to the ovaries,
5 shouldn't exposure to -- exposure to talc be far
6 greater in concentration in the rectal, vulvar,
7 vaginal, cervical and uterine tissues which are closer
8 to the area of initial exposure?

9 "ANSWER: Well, the acute exposure would be
10 greater."

11 That was your testimony. Correct?

12 A. What page are you on?

13 Q. 198, lines 8 through 17.

14 Your answer at lines 16 and 17 was:

15 "ANSWER: Well, the acute exposure would be
16 greater."

17 Correct?

18 A. I did say that, yes.

19 Q. At the time you formed your opinions in this
20 case, you were not aware of any studies showing
21 inflammation or oxidative stress as a result of
22 genital talc use in any of the areas of the
23 reproductive tract that we just discussed. Is that
24 true?

25 A. I'm sorry. I'm going to ask you to repeat the

1 question a third time.

2 Q. At the time you formed your opinions, meaning at
3 the time you provided your report which is in front of
4 you, you were not aware of any studies showing
5 inflammation or oxidative stress as a result of
6 genital talc use in any of the areas of the
7 reproductive tract that we just mentioned?

8 A. The perineum, correct?

9 Q. No. I was talking about the rectal area, the
10 vulvar, the vaginal area, the cervical, uterine
11 tissues --

12 A. No, I was not.

13 Q. It is your opinion -- and this is on page 8 of
14 your report, Exhibit C 9.

15 It is your opinion that out of all of the
16 tissue in the female reproductive system, including
17 vaginal tissue, uterine tissue, cervical tissue, the
18 ovarian tissue is the tissue within the female
19 reproductive track that is most at risk for the effect
20 of talcum powder?

21 A. That's my opinion.

22 Q. That's on page 8 of Exhibit C 9, the paragraph
23 under Roman numeral III, the last two sentences you
24 write:

25 "Because the ovaries have no intrinsic

1 elimination system, the transport of talc particles
2 and their constituents reaches the ovaries where it
3 stalls and sequesters. For these reasons ovarian
4 tissue is most at risk for the carcinogenic effect of
5 these substances."

6 Did I read that right?

7 A. Yes.

8 Q. The reason you say that is your opinion is that
9 the ovaries lack what you describe as this intrinsic
10 elimination system. Right?

11 A. That's correct.

12 Q. You have not conducted any tests to show that
13 exposure of the ovaries to particulate matter is
14 longer than exposure to other parts of the
15 reproductive system, have you?

16 A. I have not conducted any tests, no.

17 Q. And the phrase "intrinsic elimination system,"
18 you have no idea whether that is a recognized term of
19 art that is used by gynecologists; do you?

20 A. I don't believe it is. It's just my own
21 language.

22 Q. Is "intrinsic elimination system" a recognized
23 term of art used by oncologists?

24 A. I don't know.

25 Q. How many studies are cited in the body of your

1405

1 report here under Roman II to support your theory that
2 the ovaries do not have an intrinsic elimination
3 system?

4 A. None.

5 Q. Let me change topics and talk about Bradford
6 Hill.

7 A. I was just going to say that's basic anatomy.

8 Q. You cite no studies for the proposition.
9 Correct?

10 A. That's correct.

11 Q. You looked at the Bradford Hill factors in
12 formulating your opinion talc causes ovarian cancer.
13 Right?

14 A. Correct.

15 Q. One of the factors to which you gave the most
16 weight was the strength of association. Correct?

17 A. Correct.

18 Q. You thought and wrote in your report that the
19 evidence here of the strength of association was
20 compelling. That's the word you used. Right?

21 A. Yes.

22 Q. Let me ask you some questions about the fit
23 between that characterization of the strength of
24 association and some of the studies to which you
25 cited. Okay?

1406

1 A. All right.

2 Q. In your opinion the epidemiologic study supports
3 a strong association between perineal use of talc and
4 ovarian cancer. Right?

5 A. Yes.

6 Q. You used the word "strong" in your report. Do
7 you remember that?

8 A. Yes, I do.

9 Q. In your opinion, those studies show about a
10 30 percent increased risk of ovarian cancer in talcum
11 powder products users. Right?

12 A. Yes.

13 Q. That is an odds ratio of 1.3. Correct?

14 A. Correct.

15 Q. In your experience, Dr. Carson, epidemiologists
16 consider a 1.3 odds ratio to be a weak or modest
17 association. Isn't that true?

18 A. That's correct. When epidemiologists look at a
19 study and see an odds ratio between 1 and 2, they call
20 it weak or modest. When it's greater than 2, they
21 give it a stronger terminology.

22 My characterization of it as a strong
23 association has to do with the translation of that
24 increased risk to 3,000 ovarian cancer deaths in the
25 United States every year. Because of that, I believe

1 there is a strong association here. These are
2 significant studies.

3 Q. Let me unpack what you just said.

4 First, we do agree in your experience
5 epidemiologists consider a 1.3 odds ratio to be a weak
6 or modest association. Correct?

7 A. Yes.

8 Q. Epidemiologists in your experience do not
9 consider a 1.3 odds ratio to be strong association.
10 Correct?

11 A. In terms of epidemiology terminology, no.

12 Q. In fact, the example you gave a moment ago is
13 even a 2.0 odds ratio would be modest?

14 A. Modest or anything above 2 is sometimes
15 considered strong or robust.

16 Q. Now, what you just said a moment ago at the tail
17 end of your answer was that you mentioned 3,000 lives
18 saved, or something to that effect. Right?

19 A. Yes.

20 Q. And you testified that eliminating talcum powder
21 as a risk could result in saving 3,000 lives in the
22 U.S. every year, something to that effect. Right?

23 A. I did, yes.

24 Q. You came to that 3,000 number based on the
25 number of new cases of ovarian cancer in the last

1 year. Right?

2 A. I made an estimate of that, that arrived at that
3 number based on the range of what's known about the
4 prevalence of regular talcum powder use among women in
5 the United States and the annual occurrence of new
6 diagnoses of epithelial ovarian cancer, and that
7 30 percent increased risk that would result in 3,000
8 additional cases per year.

9 Q. You do not know how many of the women diagnosed
10 with ovarian cancer in any given year used talcum
11 powder. Right?

12 A. That's correct.

13 Q. Your assertion that 3,000 lives could be saved
14 relies upon an assumption that perineal talc use does
15 in fact cause ovarian cancer?

16 A. It does rely on that assumption. But responding
17 in greater detail to your previous question, I'm
18 relying on the studies that show a 30 percent
19 increased risk on the average. I haven't done that
20 science myself, but I'm using their science to build
21 my opinions and my estimate of the number of lives to
22 be saved.

23 Q. You are assuming causation to get to the 3,000
24 number; are you not?

25 A. Yes. You are right.

1 Q. Ovarian cancer is not a single disease.

2 Correct?

3 A. That's correct.

4 Q. Now, the purpose, can we agree, of conducting a
5 Bradford Hill analysis is to determine whether or not
6 an association is causal?

7 A. Correct.

8 Q. So to be clear on your methodology, for purposes
9 of this case, what you are doing when you say that
10 3,000 lives could be saved in response to my question
11 about the strength of association, what you are doing
12 is assuming causation, which is the ultimate question
13 in a Bradford Hill analysis, and, second, you are
14 using that assumption to support the analysis of a
15 specific Bradford Hill factor; are you not?

16 A. Not really. If I'm looking at the epidemiology
17 in this question, and I'm seeing consistent
18 statistical significant studies showing me there is a
19 30 percent increased risk, then I can use those other
20 pieces of information to determine there is 3,000
21 cases of ovarian cancer per year that could be
22 potentially prevented by eliminating talcum powder
23 hygienic use.

24 Q. Again, we are going around because in order to
25 do that, you are making an assumption there is a

1410

1 causal association as opposed to a mere association.

2 Correct?

3 A. It is not circular reasoning. It is simply
4 using the 30 percent increased risk shown by the
5 epidemiological studies.

6 Q. You are not a statistician or biostatistician?

7 A. You just presented a paper I published on
8 statistical methods.

9 THE COURT: Would you just answer that
10 question the way he phrased it, please.

11 Q. You are not a statistician or biostatistician,
12 are you?

13 A. I don't put myself out professionally as a
14 biostatistician or a statistician, but I certainly am
15 versed in methodology related to statistics and use it
16 all the time in both conducting and interpreting
17 research. I also teach it.

18 MR. WILLIAMS: Permission to read, your Honor?

19 THE COURT: Yes.

20 Q. Page 253, lines 14 through 16:

21 "QUESTION: Dr. Carson, you are not a
22 statistician. Correct?

23 "ANSWER: That's correct.

24 "QUESTION: You are not a biostatistician. Is
25 that right?

1411

1 "ANSWER: That's right."

2 Now, Doctor, by your own admission you are not
3 an expert in epidemiology. Correct?

4 A. I am not an expert, but I am a faculty member at
5 the Department of Epidemiology at the University of
6 Texas, School of Public Health, and some people
7 consider me an expert for that reason.

8 Q. Do you consider yourself an expert in
9 epidemiology?

10 A. Not in comparison to my other colleagues who do
11 that all the time and nothing else.

12 MR. WILLIAMS: Permission to read, your Honor.

13 THE COURT: Yes.

14 Q. Page 239:

15 "QUESTION: Do you consider yourself an expert
16 in epidemiology?

17 "ANSWER: No."

18 Now, for the purposes of your Bradford Hill
19 analysis of strength -- and I would like you to focus
20 on that factor -- your opinion was an odds ratio of
21 1.3 supports a strong association between the perineal
22 use of talc and ovarian cancer. Correct?

23 A. Yes.

24 Q. And you also call it compelling at a different
25 place in your report. True?

1412

1 A. Correct.

2 Q. One of the studies that you cite for this
3 proposition is Terry 2013. Is that true?

4 A. Yes.

5 Q. Let's look at Exhibit A 139. A 139 is the Terry
6 2013 pooled analysis. Is that correct?

7 A. Yes.

8 Q. Please look at the abstract on page 2 of Exhibit
9 A 139, about midway down, we highlighted it, it says:

10 "Genital powder use was associated with a
11 modest increased risk of epithelial ovarian cancer
12 relative to women who never used powder."

13 Correct?

14 A. That's correct.

15 Q. The authors called it "modest"?

16 A. They did.

17 Q. They didn't call it strong or compelling.

18 Correct?

19 A. Not in this case, that's correct.

20 Q. You also cite another epidemiological study,
21 Berge 2017, in support of your assertion there is a
22 strong and compelling association. Correct?

23 A. Yes.

24 Q. That's Exhibit A 11. I'll direct your attention
25 to the abstract on page 2. It says:

1 "This meta-analysis resulted in a weak but
2 statistically significant association between genital
3 use of talc and ovarian cancer."

4 And it goes on. Do you see that?

5 A. Yes.

6 Q. The authors in Berge called it "weak." Right?

7 A. They did.

8 Q. Not strong or compelling. Right?

9 A. Right.

10 Q. Please turn to page 7 of Exhibit A 11. In the
11 second paragraph below, the discussing heading, it
12 says:

13 "This meta-analysis suggests that genital
14 powder use is associated with a small increased risk
15 of developing ovarian cancer."

16 Did I read that right?

17 A. I see it.

18 Q. Now, let me have you look at page 10 of Exhibit
19 A 11, left-hand column, up at the top, it's the
20 conclusion the authors write:

21 "In conclusion, our meta-analysis identified a
22 small but statistically significant association."

23 And then it goes on. Right?

24 A. Yes.

25 Q. The authors of Berge refer to association

1414

1 between talcum powder use and ovarian cancer as small,
2 two separate times in the paper. We just showed them.
3 Right?

4 A. Yes.

5 Q. You cite Berge in support of your opinion that
6 the association between talcum powder exposure and the
7 development of ovarian cancer is strong. Right?

8 A. Yes.

9 Q. Let me ask you about your report and how your
10 report deals with cohort studies.

11 THE COURT: Are you going to a new area?

12 MR. WILLIAMS: Yes.

13 THE COURT: I think the reporter would like a
14 break.

15 MR. WILLIAMS: Thank you, your Honor.

16 THE DEPUTY CLERK: All rise.

17 (Recess.)

18 (Continued on the next page.)

19 ///

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1 THE DEPUTY CLERK: All rise.

2 THE COURT: Thank you.

3

4

5 **ARCH CARSON**, resumed.

6

7 CROSS-EXAMINATION (continued)

8 BY MR. WILLIAMS:

9 Q. Doctor, before the break I said I wanted to ask
10 you some questions about the cohort studies. None of
11 the prospective cohort studies that you examined found
12 a significant overall risk, relative risk between
13 perineal talcum powder use and ovarian cancer.

14 Correct?

15 A. That's correct.

16 Q. The Nurses' Health Study, which is one of the
17 studies you looked at, was updated in 2010. Do you
18 recall that?

19 A. Well, there was some updating but changes in the
20 methodology.

21 Q. The initial finding recorded in the Gertig 2000
22 study of an increased risk of serous invasive ovarian
23 cancer was not supported in the update in the Nurses'
24 Health study. Correct?

25 A. Well, the methodology was changed and actually

1 the study group was also different between those two
2 versions.

3 MR. WILLIAMS: Permission to read, your Honor?

4 THE COURT: Yes.

5 Q. Page 237, lines 7 through 20:

6 "QUESTION: The cohort studies, prospective
7 cohort studies have not shown an association between
8 talc and ovarian cancer. Correct?

9 "ANSWER: They have in some subtypes.

10 "QUESTION: There was an initial description
11 with respect to the first Nurses' Study that was not
12 supported in the update of that study. Is that
13 correct?

14 "ANSWER: The Nurses' study?

15 "QUESTION: Yes.

16 "ANSWER: That's correct."

17 You conclude the three prospective cohort
18 studies showed positive nonsignificant trends. Is
19 that what you wrote in your report?

20 A. Yes.

21 Q. What you mean by "positive nonsignificant
22 trends" is that the studies had positive but not
23 statistically significant relative risks. Correct?

24 A. That's correct.

25 Q. In Gonzales 2016, the relative risk was

1417

1 negative. True?

2 A. That's correct.

3 Q. The relative risk was 0.73, which is below 1.0.

4 Right?

5 A. That's correct.

6 Q. That is not statistically significant. True?

7 A. Correct.

8 Q. Now, let me step back for a second and ask you
9 about your report in a broad sense.

10 Is it true you used care in preparing your
11 report?

12 A. Yes.

13 Q. You wanted to make it as accurate as possible?

14 A. That was an attempt, yes.

15 Q. If you felt a paper was important in forming
16 your opinions regarding the question that was given to
17 you, you included it in your paper's list of
18 references. Correct?

19 A. If it contributed significantly to my opinions,
20 yes.

21 Q. Now, you do not analyze any of the cohort
22 studies in the body of your report by name. Right?

23 A. I believe that's correct.

24 Q. None of the cohorts is even identified by name
25 in the body of your report. True?

1 A. I don't recall specifically, but I would agree
2 that's possible.

3 Q. None of the cohort studies is listed in the six
4 pages of references included at the end of your
5 report, pages 11 through 16, and that's Exhibit C 9
6 that we have been looking at today. That list of
7 references goes on from page 11 all the way through
8 page 16. Am I right?

9 A. Yes.

10 Q. None of the cohort studies is listed there.
11 Right?

12 A. That's possible.

13 Q. Meaning you only reviewed the cohort studies in
14 the preparation of your report, but you did not feel
15 they contained information that was necessary to cite
16 in your report. Right?

17 A. I believe that's correct.

18 Q. Can we agree that you as a scientist cite the
19 studies that are helpful to your opinion, but do not
20 cite the studies that contradict your opinion. You
21 are cherry-picking?

22 A. I don't believe that I cited only studies that
23 were in line with my opinions. I just didn't believe
24 those three cohort studies contributed to the opinions
25 that I expressed. I did cite to the meta-analyses

1 that included them and looked at those data. So they
2 are included within those meta-analyses, and that was
3 much more fundamental to my opinions.

4 Q. Can you and I agree the scientific method
5 requires consideration of evidence that is contrary to
6 your hypothesis as well as evidence that is in favor
7 of it?

8 A. Yes, I agree with that.

9 Q. One of the studies you cited -- I think you
10 mentioned it inferentially a moment ago -- was the
11 Penninkilampi study. Right?

12 A. Yes.

13 Q. That's Exhibit A 109. I want to go to page 15.
14 I believe there is a table on that page. This table
15 lists the studies that were analyzed in the
16 Penninkilampi study. Correct?

17 A. Correct.

18 Q. And it mentions the Gonzales study from 2016,
19 the Houghton study from 2014, and the Gertig study
20 from 2000. Correct?

21 A. Correct.

22 Q. It does not list the Gates study from 2010.
23 Correct?

24 A. That's correct.

25 Q. Do you think it is important -- strike that.

1 Do you believe that Gates 2010 is an important
2 cohort study in this area of analysis?

3 A. Gates 2010 was the same data set or an
4 overlapping data set with the Gertig study. You can't
5 do a meta-analysis and double-count subjects.
6 Penninkilampi picked Gertig.

7 Q. And you chose to look only at the Gertig study
8 from 2010 rather than the study from -- strike that.

9 You used only the Gertig study from year 2000
10 rather than the Gates study from 2010. Correct?

11 A. Well, I also cited the Wera Berge study which
12 looked at the same study, and chose the Gates study in
13 favor of the Gertig study. So I cited both of those.

14 Q. Statistical power is the likelihood a study will
15 detect an effect when there is an effect to be
16 detected. Right?

17 A. That's correct.

18 Q. In your opinion, the cohort studies relating to
19 genital talc use and ovarian cancer did not have
20 sufficient power to detect a meaningful difference
21 among the subjects. True?

22 A. For the question that was asked, that's correct.

23 Q. In your opinion, the investigators in the cohort
24 studies were, I think you used the phrase, spinning
25 the roulette wheel in terms of the ability of the

1 studies to detect a difference among the subjects.

2 Correct?

3 A. Yes, I remember saying that.

4 Q. Are you familiar with the concept of a power
5 calculation?

6 A. I am.

7 Q. You did not perform any power calculation to
8 reach an opinion that the cohort studies did not have
9 sufficient power to detect a meaningful difference
10 amongst subjects. Correct?

11 A. No, but my opinion that they were underpowered
12 is not an isolated opinion. It's expressed by those
13 who performed these meta-analyses later in 2018, and I
14 believe that was also the opinion of the witness you
15 heard last Thursday, Dr. McTiernan.

16 Q. Do you remember the analysis in the Berge study
17 where they specifically treated the question of
18 whether there was sufficient power and whether power
19 could be used as a basis for criticizing the cohort
20 studies?

21 A. I don't recall specifically. I would have to
22 look at the Berge study.

23 Q. Before I get to that, the only analysis that you
24 did to conclude that the cohort studies were
25 underpowered was to read the studies and look at their

1 conclusions. Correct?

2 A. Yes.

3 Q. So, basically, what you did was you basically
4 did a visual estimation of power by just reading the
5 study?

6 A. No, I didn't. I looked at the opinions of the
7 authors of the meta-analyses who opined that those
8 cohort studies likely suffered from an underpowered
9 condition, and when they reanalyzed them as a group
10 with a larger sample size, they were able to increase
11 the power and were able to detect an effect.

12 Q. The Berge study is one of the studies upon which
13 you relied. Right?

14 A. Yes.

15 Q. Which is Exhibit A 11. Over on the right-hand
16 side of this page it says:

17 "It should be noted that the cohort studies
18 included in the meta-analysis comprised a total of 429
19 ovarian cases exposed to genital talc and 943
20 unexposed cases. The statistical power of the
21 meta-analysis of these cohort studies to detect a risk
22 ratio of 1.25 similar to the result of the
23 meta-analysis of case control studies was .99. Thus,
24 low power of cohort study cannot be invoked as
25 explanation of the heterogeneity of results."

1 Do you see that?

2 A. I see that. I think you may be interpreting it
3 incorrectly.

4 Q. Well, you understand the heterogeneity of
5 results that this is referring to is the heterogeneity
6 between the conclusions and findings of the cohort
7 studies on the one hand and the case-control studies
8 on the other. Right?

9 A. In part, yes. There is also heterogeneity
10 between the cohort studies.

11 Q. Have you read Dr. McTiernan's deposition in this
12 case?

13 A. I have not.

14 Q. Are you aware one way or the other whether
15 Dr. McTiernan did her own power calculation where she
16 concluded the number of cases, cancer cases that would
17 be necessary for the cohorts to exhibit power?

18 A. Yes, I am.

19 Q. And you are aware the number of cases that she
20 felt would be needed was less than -- significantly
21 less than the total number of cancer cases reported in
22 Berge; are you not?

23 A. Yes.

24 Q. Let me ask you the basis for your belief that
25 there was not sufficient power in the cohort studies.

1 What analysis did you do to conclude the cohort
2 studies, the four cohort studies are underpowered?

3 A. I did not determine the power of the cohort
4 studies specifically. As I discussed in my
5 deposition, I discussed the influences of various
6 factors in cohort studies and the design of cohort
7 studies that tend to go toward many cohort studies
8 being underpowered when they are conducted.

9 Q. Isn't it true, Dr. Carson, that in response to
10 the very question I asked you just now, namely, what
11 analysis you did to conclude that the cohorts were
12 underpowered, what you said is that you just read the
13 studies, looked at their conclusions, and their
14 conclusions were not that the effect didn't exist, but
15 that they couldn't detect it. Do you remember saying
16 that?

17 A. That's exactly right, and that's what happens in
18 an underpowered study.

19 Q. Am I correct anytime a study does not detect an
20 association in your view it is underpowered?

21 A. No. When studies are underpowered, they do not
22 have the ability to detect a relationship.

23 Q. Isn't another explanation, Doctor, for the lack
24 of association found in the cohorts between perineal
25 use of talc and ovarian cancer, that there was no

1 increased risk to detect?

2 A. Well, in the absence of the meta-analyses, that
3 might be a realistic hypothesis, but the meta-analyses
4 pretty much blew that out of the water when they
5 reanalyzed those studies as a group and found
6 statistically significant positive risk ratios.

7 Q. Let me ask you about Health Canada. Health
8 Canada published a draft screening assessment on
9 December 18th of last year. Right?

10 A. I'm not sure of the date, but it was at the end
11 of last year.

12 Q. At the time you prepared your expert report in
13 this matter, that draft assessment was not available
14 to you, though. Correct?

15 A. I believe that's the case.

16 Q. You are familiar with the precautionary
17 principle as it relates to the specific demonstration
18 of cause and effect?

19 A. I am.

20 Q. The precautionary principle is a general precept
21 that is used in the European union and in Canada.
22 Right?

23 A. Yes.

24 Q. The precept used in the United States is
25 different. Correct?

1 A. It is.

2 Q. In the United States the precept that is used is
3 that there needs to be scientific evidence of a harm
4 in order to take action regarding a product. Correct?

5 A. There is a difference in style, as you've
6 described it, in the United States where we require
7 hard evidence of causation in order to do anything
8 which includes legal action, it includes regulatory
9 activities, and so forth, which does not necessarily
10 exist in Canada and the European Union and some other
11 areas where the precautionary principle is used, in
12 which case, when there is a strong suspicion of a
13 problem, they stop the problem while they are doing
14 the research until it is proven not to be a problem.

15 Q. To be clear, Health Canada does not require a
16 finding of causation in order to recommend some
17 preventive action. Correct?

18 A. That's correct.

19 Q. The precautionary approach does not require that
20 talc be more likely than not capable of causing
21 ovarian cancer. Correct?

22 A. That's true.

23 Q. The principle in the U.S. is there needs to be
24 scientific evidence in order to take that
25 precautionary action. Right?

1 A. Yes.

2 Q. You do understand this proceeding is in federal
3 court in the United States before Her Honor in New
4 Jersey. Correct?

5 A. Yes. And I think that's what we're trying to
6 get to in this proceeding.

7 Q. So true or not true, you rely on what the
8 Canadian regulators who are applying the precautionary
9 principles say in a draft assessment, but not on other
10 United States public health organizations like the
11 National Cancer Institute or the FDA. Correct?

12 A. Well, I think if you look at just the state of
13 the science and where these regulatory bodies have
14 come down and have published, the Health Canada report
15 is clearly more current and more inclusive than any of
16 the others that have been published thus far, and for
17 that reason I gave it stronger consideration when I
18 finally received it.

19 Q. Let's take a look at it. Please take a look at
20 Exhibit A 58, and, in particular, page 22 there is a
21 table there, 6-1? Do you see that table?

22 A. Yes.

23 Q. This table lists the available human
24 epidemiological studies investigating the association
25 of perineal talc use and ovarian cancer. Right?

1 A. That's correct.

2 Q. It cites to the -- I'm not sure of the
3 pronunciation -- Taher study. Do you see that in the
4 preamble to the chart?

5 A. I do.

6 MS. O'DELL: If you can put up the whole
7 table. I think it continues on.

8 MR. WILLIAMS: I believe that is the whole
9 table.

10 MS. O'DELL: It continues on page 17.

11 MR. WILLIAMS: Your Honor, I can't put up two
12 pages at the same time.

13 THE COURT: While under the representation
14 this is only a part of it, and continues on the next
15 page.

16 BY MR. WILLIAMS:

17 Q. Taher 2018 is an unpublished manuscript. Right,
18 Doctor?

19 A. It is published but it has not yet been
20 peer-reviewed.

21 Q. That's what it means here when it says "here in
22 preparation"?

23 A. That's my understanding.

24 Q. Table 6-1 has a column for "study conclusion."
25 Do you see that?

1 A. Yes.

2 Q. The third column?

3 A. Yes.

4 Q. It has a column for the odds ratio with a
5 95 percent confidence interval?

6 A. Yes.

7 Q. Let's turn to page 23 of Exhibit A 58.

8 A. All right.

9 Q. I would like to refer to the second row of the
10 table on page 23. That shows the results of Green, et
11 al, 1997; does it not?

12 A. Yes.

13 Q. The odds ratio there was 1.3 with a confidence
14 interval of 1.10-to-1.54. Correct?

15 A. Correct.

16 Q. The confidence interval does not cross 1.
17 Correct?

18 A. That's correct.

19 Q. The Health Canada draft assessment reports the
20 study's conclusion as positive association. Do you
21 see that?

22 A. I see that.

23 Q. Do you agree with that characterization?

24 A. I don't recall. I would have to look at the
25 Green study to determine that.

1430

1 Q. Based upon the point estimate and confidence
2 interval that is reported right here in the fourth
3 column, do you see that shows a positive association,
4 assuming those numbers are right.

5 A. Assuming the design of the study is addressed by
6 those numbers, yes.

7 Q. If we move down to the next row, Harlow and
8 Weiss 1989, the odd ratio is 1.10. Right?

9 A. That's correct.

10 Q. It has a confidence interval of .70 to 1.73.
11 Right?

12 A. That's correct.

13 Q. The confidence interval crosses the 1?

14 A. It does.

15 Q. And the Health Canada draft assessment reports
16 that study's conclusion as no association. Do you see
17 that?

18 A. Yes.

19 Q. That column uses that "no association" phrase
20 with respect to each and every one of the studies that
21 has a confidence interval that crosses 1. Correct?

22 A. Yes, I believe so.

23 Q. Is it improper in your opinion for Health Canada
24 to report that result as "no association"?

25 A. No, it's not.

1 Q. Let me ask you to look at what has been marked
2 as Carson Exhibit 517, which is in your second binder.

3 MR. WILLIAMS: Your Honor, it would be in your
4 third.

5 Q. This is a July 2018 presentation provided to us
6 by plaintiffs' counsel, a present relationship by
7 Daniel Krewski. Daniel Krewski is one of the authors
8 of the Taher 2018 meta-analysis; is he not?

9 A. I don't know.

10 Q. Let's take a look at Exhibit A 137, which is
11 Taher 2018. This is the second page and the last one
12 listed, who is the senior person. Correct?

13 A. Yes, usually.

14 Q. That's Daniel Krewski. Correct?

15 A. Yes.

16 Q. Let's go back to the Krewski presentation. I'll
17 ask you to look at page 31 of that presentation,
18 Exhibit 517. There is a slide there that says:
19 "Cancer classification."

20 Do you see that?

21 A. Yes.

22 Q. The first row shows IARC's classification from
23 2010 for talc, and it references in the second column
24 the 2B designation. Correct?

25 A. That's correct.

1 Q. You are familiar with the IARC designations.

2 Right?

3 A. I am.

4 Q. You included the IARC monograph on the reference
5 list for your expert report. Right?

6 A. Yes, I did.

7 Q. Now, IARC rejected classifying talc as a
8 carcinogenic. True?

9 A. Actually, Group 2B is a carcinogenic
10 classification.

11 Q. IARC rejected classification of talc as a
12 carcinogenic, instead assigning it to the
13 classification of possibly carcinogenic to humans. Is
14 that correct?

15 A. That's correct.

16 Q. IARC has categories for known or probable
17 carcinogens which is Category 1 or Category 2A.

18 Right?

19 A. That's correct.

20 Q. IARC did not classify talc in either of those
21 categories. Right?

22 A. No. But I reiterate, 2B is a carcinogen
23 classification within the IARC scheme.

24 Q. And 2B has a specific meaning within that IARC
25 scheme. Correct?

1 A. It does, possible human carcinogen.

2 Q. Now, you wrote:

3 "IARC classified perineal talc use as possibly
4 carcinogenic to humans on the basis of insufficient
5 evidence of carcinogenesis in humans but strong
6 evidence in other mammalian species."

7 Do you remember that?

8 A. I do remember that.

9 Q. Let me have you look at your report, Exhibit
10 C 9, page 4, paragraph B. Under the heading "Talcum
11 Powder and Cancer," Part B, you reference the 2006
12 IARC evaluation. Right?

13 A. I do.

14 Q. And what you wrote was:

15 "Meaning that there is insufficient evidence
16 of carcinogenesis in humans but strong evidence in
17 other mammalian species."

18 That's what you said?

19 A. Yes.

20 Q. That is not what a 2B classification means, is
21 it?

22 A. Well, in the context of the IARC preamble, that
23 is one of the categories for 2B classification. I
24 believe I was in error in specifically stating that
25 language, however.

1 Q. Right. Let's take a look to see what we're
2 talking about.

3 Exhibit A 72 is IARC 2010 monograph. Let's
4 look at the specific evaluation of talc on paper 423
5 of that document of Exhibit A 72.

6 There it says:

7 "There is limited evidence in experimental
8 animals for the carcinogenicity of talc not containing
9 asbestos or asbestiform fibers."

10 Correct.

11 A. That is correct.

12 Q. IARC did not say, as you said in your report,
13 that there was strong evidence in other mammals.
14 Correct?

15 A. Correct.

16 Q. IARC did not say there was sufficient evidence
17 in other mammals. Right?

18 A. Correct.

19 Q. In IARC's view, the association was modest, not
20 strong. Right?

21 A. I don't see the word "modest" in here, but they
22 classed it as 2B.

23 Q. Let's look at page 423 of Exhibit A 72 under the
24 heading "rationale." IARC observed:

25 "For perineal use of talc-based body powder,

1435

1 many case-control studies of ovarian cancer found a
2 modest but unusually consistent excess in risk
3 although the impact of bias and potential confounding
4 could not be ruled out."

5 Did I read that right?

6 A. Yes, you did.

7 Q. Designating talc as a 2B possible carcinogen,
8 IARC specifically concluded they could not rule out
9 bias and confounding factors. True?

10 A. That's correct.

11 Q. Now, let's go back to the exhibit we were
12 looking at, Carson 517, which was that report that was
13 prepared by one of the Taher authors, Dr. Krewski.
14 Page 31 describes the conclusion of Health Canada and
15 it references Group 3, Roman numeral III A, possibly
16 carcinogenic to humans. Correct?

17 A. Yes.

18 Q. The conclusion that Dr. Krewski, one of the
19 authors of Health Canada's draft assessment, "was data
20 from epidemiological studies indicate an association
21 between exposure and human cancer, but alternative
22 explanations such as chance, bias, or confounding
23 cannot be excused."

24 Did I read that right?

25 A. You did.

1436

1 Q. In that specific respect, the Krewski analysis,
2 the Taher analysis, and the IARC 2006 analysis, were
3 consistent. Correct?

4 A. Yes. I don't think this is an official document
5 of any kind.

6 Q. To be sure, it is a draft assessment. Right?

7 A. Well, the Health Canada assessment is a draft
8 assessment that the organization felt was important to
9 publish in advance of it becoming final. But this
10 presentation that you are quoting from is not an
11 official document.

12 Q. Is it your testimony that the draft assessment
13 says that chance, bias, and confounding could be ruled
14 out by Health Canada?

15 A. No, that's not my testimony.

16 Q. Let me ask you -- and I have one topic after
17 this, the Taher study.

18 Could we go to the next slide before I turn to
19 that.

20 Funding source, it says for this document that
21 it was done at the request of Health Canada; does it
22 not?

23 A. Yes.

24 Q. Now, to the Taher study. This is Exhibit A 137.
25 This is Dr. Krewski's has-yet-to-be, peer-reviewed

1 article. I would like to direct your attention to
2 page 42. You've read this. Right?

3 A. Yes.

4 Q. Midway down this paragraph there is a sentence
5 that says:

6 "This latter review process provides some
7 insights concerning possible mechanisms of talc
8 toxicity including oxidative stress, immune system,
9 altercations, and inflammatory responses. However, it
10 also indicates that talc is not genotoxic."

11 Did I read that correctly?

12 A. Yes, you did.

13 Q. It goes on to say:

14 "In total, the epidemiology studies suggest
15 that perineal exposure to talc power is a possible
16 human ovarian carcinogen, but there are concerns that
17 the actual exposure experienced by these women over
18 the 40 to 50 years is not well understood."

19 Did I read that right?

20 A. Yes, you did.

21 Q. The analysis of the Taher authors was, all
22 things considered, talc is not genotoxic. Correct?

23 A. This one paragraph is taken out of context.
24 Taher goes on to do some significant explaining of
25 these various things and to draw a synthesis. This is

1 a single study. This is not the Health Canada report.
2 This is the Taher study that contributed to the Health
3 Canada report.

4 Q. Understood. But the Taher study, at least by
5 its own terms, says that the data indicates that talc
6 is not genotoxic. Right?

7 A. That you have the review that was done that
8 indicated it was those things but not genotoxic.

9 Q. Last topic, very quickly.

10 You testified earlier today in the context of
11 heavy metals, whether they can be a carcinogenic. You
12 testified that the fact that heavy metals are
13 carcinogenic in one type of tissue raises suspicion
14 that the same mechanism would operate in ovarian
15 tissue. Do you remember that testimony?

16 A. Yes.

17 Q. And you said, and I'm quoting:

18 "It raises the suspicion of cancer. We can
19 assume the same mechanism can operate in ovarian
20 tissue."

21 Do you remember saying that?

22 A. Yes.

23 Q. That's total speculation on your part; is it
24 not?

25 A. No, that's general toxicological principle.

1 Q. There are different cancers that may be
2 associated with different chemicals or agents.
3 Correct?

4 A. That's correct.

5 Q. And you can have an agent that is a carcinogen
6 or a probable or possible carcinogen for one type of
7 cancer, but not for another type of cancer. Correct?

8 A. You are asking me if you can have an agent that
9 is causal for one type of cancer but not for another
10 type of cancer?

11 Q. Correct.

12 A. Of course.

13 Q. You can have an agent or a chemical that is a
14 carcinogen for one route of exposure for a chemical or
15 agent but is not carcinogenic for a different route or
16 exposure. Correct?

17 A. That's correct.

18 Q. So the fact that heavy metals could be
19 associated with a particular type of cancer does not
20 tell us whether or not it is a root of exposure for
21 cancer with regard to other types of tissue. Correct?

22 A. I believe the term I used was it raises
23 suspicion that the same mechanism can operate in
24 another tissue including ovarian epithelial tissue.

25 Q. And raising suspicion is not the equivalent of a

1440

1 causal connection. Right?

2 A. That's correct.

3 MR. WILLIAMS: No further questions at this
4 time.

5 THE COURT: Great. Thank you.

6 THE DEPUTY CLERK: All rise.

7 (Recess.)

8 (Short recess.)

9 (In open court._)

10 THE DEPUTY CLERK: All rise.

11 THE COURT: Thank you. Everyone may be
12 seated.

13 Ms. O'Dell.

14

15 **ARCH CARSON**, resumed.

16

17 REDIRECT EXAMINATION

18 BY MS. O'DELL:

19 Q. Dr. Carson, first I'm going to turn to your
20 deposition. Mr. Williams read from your deposition
21 quite a bit and maybe failed to include all the
22 pertinent portions, from my perspective, at least.

23 Mr. Williams read a number of passages from
24 page 298 through 299. If we go to the bottom of page
25 299, line 18, there was a question and you were

1 talking in that regard in terms of line 11:

2 "QUESTION: There are ways to study whether
3 two toxins combined increase a risk more than exposure
4 to a single toxin, whether one offsets the risk of one
5 of the toxins or whether you multiply them. Right?

6 "ANSWER: Yes.

7 "QUESTION: Has any such study ever been done
8 with regard to talc and heavy metals that you identify
9 in your report?

10 "ANSWER: Not specifically a study to look at
11 the combined contribution, but we know a lot about the
12 mechanism of action of the metals in particular in the
13 microenvironment; and based on what we know about the
14 mechanism of action of talc as well as even asbestos,
15 they are all similar, and, for that reason would be
16 expected to be additive."

17 Is that your testimony, Doctor?

18 A. It is.

19 Q. If you turn your attention, now, Dr. Carson, I
20 think you have your deposition in front of you,
21 Mr. Williams read from page 198 and, specifically, he
22 read from beginning at line 8 of 198. It says:

23 "QUESTION: If talcum powder migrates from the
24 perineal region to the ovaries, shouldn't exposure to
25 talc be far greater in concentration in the rectal,

1442

1 vulvar, vaginal, cervical and uterine tissues, which
2 are closer to the initial exposure?

3 "ANSWER: Well, the acute exposure would be
4 greater."

5 And on page 199, starting on line 8.

6 "QUESTION: Well, in fact, there would be
7 chronic exposure. So if we're dealing with, as you
8 described in the very beginning, which you were asked
9 to look at the habitual use of talcum powder that
10 would create exposure on a chronic basis to the rectal
11 area and tissues, vulvar, vaginal, cervical and
12 uterine tissues. Is that right?

13 "ANSWER: I suspect if one doesn't bathe, that
14 would be more of an issue, but most people bathe
15 regularly as well."

16 You said that earlier today when Mr. Williams
17 said maybe you weren't accurate in your deposition
18 testimony. But were you accurate.

19 A. Yes, that was my testimony.

20 MR. WILLIAMS: Your Honor, I object to the
21 characterization of what I did. I read from the
22 transcript.

23 MS. O'DELL: My apologies.

24 THE COURT: Understood. You're all so polite.
25 Lovely. Okay.

1 BY MS. O'DELL:

2 Q. You were also asked a number of questions today
3 and actually reminded of your deposition testimony,
4 Dr. Carson, regarding the amount of metals contained
5 in Johnson's Baby Powder and Shower To Shower. Do you
6 remember those questions?

7 A. Yes, I do.

8 Q. And is it necessary to reach your opinions to
9 know the exact amount of metal in talcum powder?

10 A. It's not necessary because these metals act as
11 catalysts, and very small minute amounts of them have
12 the full force and effect in distant tissues.

13 Q. Does the presence of heavy metals, such as
14 nickel, chromium, and cobalt provide evidence of a
15 biologically plausible mechanism for the way talcum
16 powder can cause ovarian cancer?

17 A. It provides evidence of part of the mechanistic
18 process of carcinogenesis in the ovaries.

19 Q. Does it contribute to your opinion that it is
20 biologically plausible that genital use of talcum
21 powder causes ovarian cancer?

22 A. Absolutely.

23 Q. Would that also be true of the presence of
24 asbestos in talcum powder?

25 A. Yes.

1 Q. Why?

2 A. Because asbestos is a recognized carcinogen in
3 particular for the ovaries, and if it is a component
4 of an exposure we know that it will have an effect if
5 that exposure reaches the ovaries.

6 Q. Is it your opinion, based on the evidence that
7 you've looked at both in animals and humans, that
8 talcum powder products and all the constituents
9 contained in those products can reach the ovary?

10 A. Yes.

11 Q. And does the fact that the components of the
12 product can reach the ovary and the fallopian tubes,
13 of course, and they contain carcinogens like fibrous
14 talc, does that add to your opinion that it is
15 biologically plausible that talcum powder products can
16 cause ovarian cancer?

17 A. It supports that opinion.

18 Q. You were asked a number of questions about the
19 Taher meta-analysis just at the end of Mr. Williams'
20 cross-examination.

21 MS. O'DELL: General Causation Opposition
22 Exhibit No. 63 for the plaintiffs.

23 Q. If you look at page 49, was this meta-analysis
24 paid for by Health Canada?

25 A. In part this is supported by Health Canada.

1 Q. This is not a document that was a product of the
2 regulatory agency Health Canada. Is that fair?

3 A. Well, it was commissioned by Health Canada.

4 Q. But it is the product of those authors that have
5 written this meta-analysis. Is that a fair statement?

6 A. Yes, that's correct.

7 Q. And in terms of the PowerPoint that you were
8 shown that was prepared by Dr. Daniel Krewski, do you
9 recall being asked questions about that PowerPoint?

10 A. Yes, I do.

11 Q. Mr. Krewski was not acting on behalf of Health
12 Canada when he issued that PowerPoint or gave that
13 presentation?

14 MR. WILLIAMS: Lacks foundation, your Honor.

15 A. Not to my knowledge.

16 THE COURT: His answer picked up on that.

17 Thank you.

18 Q. Now, let me turn my attention to the Health
19 Canada screening assessment. It's plaintiffs general
20 causation opposition Exhibit No. 56. You were asked a
21 number of questions about the causal assessment.

22 Does this document contain a systematic review
23 of the epidemiologic literature?

24 A. Yes, it does.

25 Q. Does it contain a comprehensive review of the

1446

1 cell studies that are relevant to the question of
2 whether talcum powder causes inflammation?

3 A. Those that were available at the time that this
4 was prepared, yes.

5 Q. And in addition, does it also contain a thorough
6 analysis of the animal studies that provide evidence
7 regarding talcum powder causing inflammation?

8 A. Yes, it does.

9 Q. In fact, Dr. Carson, if you'll turn to page 15
10 of the assessment, you will see at the bottom of the
11 page they do an analysis of the animal studies. Do
12 you see that?

13 A. I do.

14 Q. And did you review this in preparation for your
15 deposition and your testimony here today?

16 A. Yes.

17 Q. And, of course, this screening assessment was
18 not available to you at the time of your expert
19 report. Is that correct?

20 A. That's correct.

21 Q. And the authors of this analysis, at the bottom
22 of page 15, also walk through some of the same animal
23 studies that Mr. Williams asked you about today.
24 Correct? See that Hamilton and the Keskin papers?

25 A. I do.

1447

1 Q. Is their evaluation of both the Hamilton and
2 Keskin papers similar to your evaluation that they
3 provide evidence that talc causes chronic
4 inflammation?

5 A. Yes, somewhat similar.

6 Q. Let me also ask you, while you have the Health
7 Canada document in front of you -- I was going to ask
8 you about pages 16 and 17. You were asked questions
9 about studies -- I think it was Green and Harlow on
10 page 17, and you were asked about the specific
11 findings of those studies.

12 Do you recall those questions?

13 A. I do.

14 Q. Would it be fair to say those studies and the
15 data presented from those studies are a snapshot in
16 time?

17 A. Absolutely.

18 Q. In particular, those studies were in 1997 and
19 1989, and there has been extensive data published
20 since that time. Fair?

21 A. Yes.

22 Q. And would it be more appropriate in terms of
23 trying to evaluate the body of evidence,
24 epidemiological evidence, that has been published
25 regarding the genital use of talc and ovarian cancer,

1 to look at some of the more recent meta-analyses, like
2 Penninkilampi or Berge?

3 A. Yes.

4 Q. Let's pull up the biologic plausible paper you
5 were asked about shortly after lunch, Exhibit No. 63.

6 Do you have it?

7 A. I do.

8 Q. Do you recall being asked questions about this
9 paper specifically, doesn't it mention talc? Do you
10 recall that line of questioning?

11 A. I do recall that line of questioning, and I
12 can't tell you without reviewing this paper whether or
13 not it does mention talc. But the upshot of the paper
14 is foreign bodies in general, not specifically talc or
15 any other thing.

16 Q. And, certainly, talc would be a foreign body.
17 Correct?

18 A. Yes.

19 Q. Is talc a particulate similar to, in some
20 instances, asbestos or some of the other particulates
21 mentioned in this paper?

22 A. Yes.

23 Q. And was the purpose -- what was the purpose for
24 you citing this paper in your expert report?

25 A. The reason I cited it was because I used it as

1 an example of scholarly opinion regarding the effects
2 of foreign bodies on tissue and the production of
3 inflammation and potentially carcinogenesis.

4 Q. You were asked a series of questions about the
5 cohorts in relation to your report and whether you
6 considered the cohort studies in reaching your
7 opinions.

8 Did you review the cohort studies in preparing
9 for your expert opinion?

10 A. I did.

11 Q. And did you -- does the fact that -- let me
12 strike that and ask you this:

13 Does the fact that you didn't cite them in
14 your expert report in any way undermine your
15 consideration of them?

16 A. No, it doesn't. I only cited things that
17 contributed significantly to my opinions in the
18 report.

19 Q. You were asked questions as well, Dr. Carson,
20 about a legal decision, a Daubert decision in which
21 you provided expert testimony that was not admitted at
22 trial. Do you recall that line of questions?

23 A. Yes.

24 Q. Would you just explain briefly the opinion you
25 expressed in the case and the circumstances.

1450

1 A. Well, this was a case of an inmate in the Texas
2 correctional system who worked in a prison that had a
3 stainless steel production shop, and he worked as a
4 stainless steel welder doing what's called TIG
5 welding, which is tungsten inert gas welding over a
6 period of more than a decade. I think it was
7 16 years. He developed throat cancer and died. I was
8 asked to look at the case and to render an opinion
9 regarding the cause of his death and whether or not it
10 was influenced by the job that he was doing.

11 I investigated the job and the circumstances,
12 determined that he was provided no personal protection
13 equipment for the respiratory system, that there was
14 improper ventilation in the work area, that he was
15 using thoriated tungsten welding rods which contained
16 2 percent of radioactive thorium, and that this
17 thorium was going up into the air in his breathing
18 zone all the time that he was welding in the form of
19 metal oxide called thorium oxide.

20 I looked up literature on this subject,
21 determined that there was very little specific
22 information regarding the health effects of inhaling
23 thoriated tungsten welding rod exhaust, but I was able
24 to find a large body of literature on another form of
25 administration of thorium oxide, a medical device

1451

1 called Thorotrast, which is a radiology contrast agent
2 that was used extensively in the 1940s and '50s, which
3 was thorium oxide injected intravenously to light up
4 areas of tissues where the circulation went. It was
5 also used in gastrointestinal studies for radiology
6 and patients receiving that developed a myriad of
7 cancers at the sites where this thorium oxide
8 concentrated and stayed, and I could use the term
9 sequestered, as I did earlier today.

10 The State put up a witness who was -- my
11 opinion was that thorium located in the throat at the
12 site of the initiation of his cancer caused genetic
13 change that progressed into a tumor which ultimately
14 killed him.

15 Q. Was your opinion in that case a case specific
16 opinion?

17 A. It was a case specific opinion regarding this
18 man.

19 Q. And in the present matter, have you been asked
20 to give any case specific opinions about specific dose
21 or exposures to any individual patient?

22 A. Well, Mr. Williams asked me a couple of
23 questions referring to a woman, which I answered in a
24 different way, but, no, I haven't responded to any
25 questions about a particular person.

1452

1 Q. And in terms of your general causation opinions,
2 do you need to know a specific amount of talcum powder
3 that has reached the ovary in order to render your
4 opinions in this case?

5 A. No, I don't.

6 Q. And why is that?

7 A. Because I know if any gets there, it will stay
8 there a very long period of time, and if more is
9 coming along all the time, that amount of talc will
10 build up in the ovaries over time and is likely to
11 produce a problem, inflammation at a minimum, and in
12 some people ovarian cancer.

13 Q. You were asked some questions on Carson 508 by
14 Mr. Williams. It was a one-page report entitled, "The
15 Lack of Ovarian Effect of Lifetime Talc Exposure in
16 F-344/in Rats and Mice" with a number?

17 Do you recall those questions, Dr. Carson?

18 A. Yes, I do.

19 Q. Mr. Williams asked you a series of questions
20 regarding the potential effects of talc on the ovary
21 in this particular study. Do you recall those
22 questions?

23 A. I do.

24 Q. Do rats have bursas?

25 A. They do.

1 Q. What's a bursa?

2 A. It's a sac that surrounds the ovaries on one
3 side and essentially provides a special isolated
4 chamber for the ovaries in rodent species.

5 Q. Would the presence of the bursa in the anatomy
6 of the rat at least in part explain why you saw no
7 effect in the ovary?

8 A. It makes rats very different, very different
9 from humans in terms of the reproductive anatomy, and
10 it makes extrapolation of rodent evidence very
11 difficult for humans.

12 MS. O'DELL: Can you pull up the PowerPoint,
13 please, and specifically the meta-analysis slides.

14 Q. Dr. Carson, looking at this data from the
15 meta-analysis and pooled studies, you were asked a
16 series of questions by Mr. Williams regarding whether
17 the epidemiologic data showed a weak association or a
18 moderate association. I'm sure you remember those
19 questions.

20 What does the actual data show regarding the
21 association between genital talc use and ovarian
22 cancer?

23 A. Well, these meta-analyses, including the Terry
24 pooled analysis, universally show a statistically
25 significant positive risk ratio associated with talcum

1454

1 powder use and the development of ovarian cancer, and
2 that the magnitude of that increased risk is about
3 1.3.

4 Q. Let's now turn to the Penninkilampi study, if we
5 can.

6 MS. O'DELL: Thank you, your Honor. I'm
7 getting close.

8 THE COURT: Fine.

9 Q. If you'll turn to Table 1 on page 5.

10 MS. O'DELL: For the record, I think this is
11 Exhibit 62 for the plaintiffs.

12 Q. Dr. Carson, does this table show a
13 dose-response?

14 A. It does show a dose-response relative to the
15 number of total applications applied by women which
16 was a method of assessing quantity of exposure.

17 Q. Would you now turn to the Ness paper. You were
18 asked questions about the Ness paper. You cited it
19 and went through it during your presentation this
20 morning. Ness 99.

21 On page 4 of the Ness paper, you see it's page
22 4 of ten, right above the section dealing with
23 endometriosis. You were shown this by Mr. Williams,
24 and we went through it this morning. It has the
25 diagram of carcinogenesis that we walked through. If

1 you look on page 4 of the paper, you see it says:

2 "Nevertheless, the consistency of an
3 association between talc use and ovarian cancer in a
4 series of well-conducted studies of varying designs
5 suggests that talc use may represent another
6 environmental exposure that enhances epithelial
7 inflammation and thereby either initiates or promotes
8 ovarian carcinogenesis."

9 Is that consistent with your opinion,
10 Dr. Carson?

11 A. Yes, it is.

12 MS. O'DELL: Can I have the summary of opinion
13 slide.

14 Q. Dr. Carson, you were asked a series of questions
15 about your reliance on Dr. Longo's testing regarding
16 the presence of asbestos in fibrous talc. Do you
17 recall those questions?

18 A. Yes, I do.

19 Q. You testified also that you relied on internal
20 documents or corporate documents regarding test
21 results. Did you consider, in addition to those two
22 types of evidence, published literature regarding the
23 presence of asbestos and fibrous talc in talc
24 deposits?

25 A. Yes.

1456

1 Q. And if Dr. Longo's report were not admitted in
2 this case -- and I can say I don't expect that, but I
3 want to ask hypothetically if that were to happen,
4 would it change any of your opinions?

5 A. It would not change any of the opinions shown on
6 this slide.

7 MS. O'DELL: I have one more question, your
8 Honor.

9 THE COURT: You are doing fine time-wise.

10 Q. I'm going to go back to Penninkilampi because I
11 realized I had forgotten something. You were asked
12 questions about heterogeneity in relation to the
13 epidemiologic literature. And turning to page 7 --
14 it's page 46 of the publication, at the bottom right
15 there on the left side, did Penninkilampi address
16 heterogeneity, Dr. Carson?

17 A. Yes, they did, and they showed that or they
18 stated that, "none of the analyses in this review had
19 statistically significant heterogeneity except for
20 nonperineal application which indicates consistency in
21 the direction and magnitude of the effect size between
22 individual studies and strengthening the reliability
23 of the pooled effect sizes."

24 Essentially, they were saying heterogeneity
25 was not an issue in this analysis.

1 Q. Dr. Carson, let me transition to another topic
2 but back to Health Canada. Did Health Canada conclude
3 there was a causal relationship between the general
4 use of talcum powder and ovarian cancer?

5 A. They stated that in their report that further
6 available data are indicative of a causal effect.

7 Q. And did they do a comprehensive review of the
8 data?

9 A. They did.

10 Q. Was the precautionary principle that you were
11 asked about by Mr. Williams, is that a regulatory
12 concept?

13 A. It is a regulatory concept. This report is all
14 based on science.

15 Q. And the fact that Health Canada operates with a
16 precautionary principle does not undermine the
17 scientific conclusion they reached in the assessment.
18 Is that fair?

19 A. That's correct.

20 Q. Last, you were asked a number of questions about
21 dose, dose of metals, dose of fragrance, dose of
22 fibrous talc in asbestos in talcum powder products.

23 Did you consider dose in terms of the use of
24 the product for duration and frequency?

25 A. Yes.

1 Q. Let me ask you a follow-up question. Why was it
2 not necessary for your opinion to evaluate the dose of
3 individual components?

4 A. Well, the individual components are just that,
5 they are components; and if you look at talcum powder
6 as a unit of exposure, those components will be in it
7 wherever it goes. And so a dose calculation or a dose
8 estimate is always useful and helpful. But absent
9 specific dose measurements that are frequent and
10 reliable, we often will use surrogates such as
11 frequency and duration in very much the same way for
12 cigarette exposure; we use something like pack years,
13 and this is a very useful and well tried and accepted
14 principle of how to do dosing in epidemiology.

15 Q. And in the context of cigarette smoking, it's
16 universally accepted cigarette smoking causes lung
17 cancer. Fair?

18 A. I think it is fairly universally accepted at
19 this point.

20 Q. Yet there is no individual dose calculation of
21 nicotine or any of the other chemicals that might
22 contribute to the carcinogenicity of those products?

23 A. That's correct.

24 Q. Is it your opinion that the existence or the
25 presence of heavy metals, fibrous talc, asbestos,

1 contribute to the biologic plausibility of genital
2 talc use causing ovarian cancer?

3 A. That is my opinion.

4 MS. O'DELL: I have nothing further, your
5 Honor.

6 THE COURT: Thank you.

7 MR. WILLIAMS: Can I have a few minutes, your
8 Honor?

9 THE COURT: Come on up.

10
11 RECROSS-EXAMINATION
12 BY MR. WILLIAMS:

13 Q. Doctor, I would like to start with the
14 Penninkilampi study. This is the slide that you went
15 over with Ms. O'Dell earlier today. Correct?

16 A. I believe so, yes.

17 Q. It was part of your presentation. Right?

18 A. Yes.

19 Q. Here at the bottom there is a reference to the
20 confirmation of an association in cohort studies
21 between perineal use of -- perineal talc use and
22 serous invasive ovarian cancer is suggestive of a
23 causal association?

24 Correct?

25 A. That's correct.

1460

1 Q. That is a sentence that makes a specific
2 reference to data concerning serous invasive ovarian
3 cancer. Correct?

4 A. That's right.

5 Q. We talked about how the Penninkilampi study did
6 not consider the Gates 2010 study. Right?

7 A. That's correct.

8 Q. It did not consider the Gates 2008 study.
9 Correct?

10 A. Right.

11 Q. And you know that both of those studies found
12 that whatever impact there was to serous invasive
13 ovarian cancer in the earlier Gertig study went away
14 over the course of those eight to 10 years. True?

15 A. Not necessarily. As I mentioned before,
16 although the Gates studies were reanalysis of the same
17 cohort that was included in the Gertig study, it was a
18 different study with a different design, and the
19 population base was different as well. So I don't
20 think you can come to that conclusion that the effect
21 went away over the intervening time period.

22 Q. But you and I can agree that the reference here
23 in Penninkilampi to data being suggestive of a causal
24 association does in fact refer to data concerning
25 serous invasive ovarian cancer in particular.

1 Correct?

2 A. Yes, that's correct.

3 Q. So you and I can disagree about the import of
4 the later studies by Gates in 2008 and 2010, but the
5 fact is that Penninkilampi does refer to serous
6 invasive in particular. Correct?

7 A. Yes.

8 Q. Now, one of the other studies that you looked at
9 is the Berge study and you know the Berge study did
10 include the data from the Gates 2010 study. Right?

11 A. That's correct.

12 Q. And when it looked and included the data from
13 the Berge -- from the Gates 2010 study, the conclusion
14 that was reached in the Berge study was --

15 MR. WILLIAMS: Can we pull up Exhibit A 11,
16 page 10, which is the final page of the Berge study.

17 Q. (Continuing) -- we do know that the conclusion
18 that was reached in Berge in that last sentence that
19 is on your screen, was that once the data included
20 Gates 2008 -- excuse me -- included Gates 2010, they
21 concluded:

22 "Several aspects of our results including the
23 heterogeneity of results between case-control and
24 cohort studies, however, do not support a causal
25 interpretation of association."

1 That was the conclusion in Berge. Correct?

2 A. That was their final sentence, yes.

3 Q. And Berge did include the later studies after
4 Gertig 2000?

5 A. Yes, that's correct. But in the highlighted
6 section at the beginning of your display there, it
7 says, "their meta-analysis identified a small but
8 statistically significant association between genital
9 talc use and risk of ovarian cancer. However, this
10 association was limited to the serous histologic type
11 and the case-control studies."

12 So they came to the same overall conclusion
13 looking at slightly different data.

14 Q. That's not true, is it, Doctor? This refers to
15 the case-control studies in that sentence you pointed
16 to, not the cohort studies. Right?

17 A. The cohort studies were, however, included in
18 that analysis.

19 Q. Not in that sentence you just read.

20 THE COURT: The first sentence is what he's
21 suggesting to you. The first sentence was listed as
22 case-control study. The last sentence he read
23 includes both.

24 Q. Correct?

25 A. Correct.

1 Q. Different topic.

2 Counsel placed up Exhibit A 58, which was the
3 analysis by Health Canada, and she directed you to
4 page 21 and the animal studies. Do you remember that
5 just now?

6 A. Yes.

7 Q. A 58, page 21.

8 At the very bottom of the page, the last line
9 refers to the Hamilton study, 1984, and it carries
10 over to the next page. Right? At the top of the next
11 page, page 22, there is a reference to Keskin 2009.
12 Right?

13 A. That's correct.

14 Q. You and I went through Hamilton 1984 and Keskin
15 2009 today. Right?

16 A. That's correct.

17 Q. What Health Canada concluded with respect to the
18 animal studies is in that next sentence where it says:
19 "No chronic or carcinogenicity animal studies
20 on perineal exposure of talc were located in the
21 literature."

22 That's a true statement. Correct?

23 A. Yes.

24 Q. You have not located any. Correct?

25 A. No, I haven't.

1 Q. And you were asked some questions about the
2 Boorman study that I showed you earlier today. Do you
3 remember that?

4 A. Yes.

5 Q. And you pointed out that rats have bursa sacs
6 around the ovaries?

7 A. That's correct.

8 Q. And you do remember we discussed Hamilton where
9 the scientists injected the ovaries through the sac
10 and into the ovary itself. You remember that, right?

11 A. I think it was into the bursal sac itself, not
12 into the ovaries.

13 Q. The ovaries are inside the bursal sac. Correct?

14 A. Yes.

15 Q. And so once the bursal sac is pierced, one is
16 within the ovaries. Correct?

17 A. No. There is a space between the sac membrane
18 and the ovaries themselves.

19 Q. Once the scientists in the Hamilton study
20 injected those bursal sacs with talcum powder, there
21 was no evidence of carcinogenicity in the animals.
22 Correct?

23 A. They did not interpret it as carcinogenicity.
24 They noted the development of papillae.

25 Q. Doctor, you cannot point the Court to any study

1 that indicates that once an ovary is subjected to
2 talcum powder, that there are carcinogenetic changes
3 in the ovary of any animal?

4 A. I have not seen studies that have done that.

5 Q. You were asked a question or two about the order
6 that affirmed a rejection of your testimony in the
7 Berleson matter from Texas. Correct?

8 A. Correct.

9 Q. In that matter, is it true that the Circuit
10 Court -- that is, the Federal Appellate Court -- found
11 that because you had not conducted a mean exposure --
12 an estimation of mean exposure level, and did not do
13 an analysis of dose, that it was appropriate for the
14 Court to not permit your testimony?

15 A. What the Court determined, based on testimony of
16 the State's witness, who was a health physicist, was
17 that the only relevant calculation for radiation
18 exposure was a whole body exposure calculation, which
19 I did not perform and that was the upshot of the
20 decision.

21 Q. Let's look very quickly here at the order. This
22 is Carson 507.

23 You see in the middle of page 12 of the order
24 there is a reference:

25 "Dr. Carson is even quoted affirming in his

1466

1 own scholarly papers that, quote, an important step in
2 studies relating to worker health and industrial
3 exposure is the estimation of mean exposure level."

4 That's a quote from your paper. Is that
5 correct?

6 A. That's correct.

7 Q. That's the same paper you that I went over at
8 the beginning of your cross-examination today?

9 A. That's correct.

10 Q. And the Court concluded because of that failure
11 your testimony should not be permitted. Correct?

12 MS. O'DELL: I object. To the degree he
13 understands the underlying facts is one thing. The
14 legal analysis I don't think is appropriate to be
15 asked about.

16 THE COURT: We're not getting into the legal
17 analysis. He was trying to distinguish what the court
18 actually did in his own testimony a moment ago as to
19 what he understood was done.

20 We'll move on.

21 BY MR. WILLIAMS:

22 Q. Last point: Do you remember, Doctor, that the
23 Court concluded -- that the Magistrate Judge found
24 that your opinion was based on "speculation, guesswork
25 and conjecture to support your theory."

1467

1 The Magistrate Judge based his conclusion on
2 the fact "Dr. Carson failed to conduct a dose
3 assessment. There was no scientific evidence linking
4 thoriated welding electrodes to lung or throat cancer,
5 and the studies Dr. Carson did rely on concerned
6 Thorotrast."

7 Do you remember that portion of the order?

8 A. Yes.

9 MR. WILLIAMS: No further questions.

10 MS. O'DELL: One question, your Honor?

11 THE COURT: Yes.

12

13 FURTHER REDIRECT EXAMINATION

14 BY MS. O'DELL:

15 Q. Dr. Carson, you were asked questions again about
16 the decision from the Court of Appeals in Texas. Is
17 there credible evidence connecting the genital use of
18 talcum powder with ovarian cancer?

19 A. Yes, there is.

20 MS. O'DELL: I have nothing further.

21 THE COURT: Thank you. You're excused.

22 (Witness excused.)

23 (Court adjourned at 4:50 p.m.)

24 ///

25

1468

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2 **I N D E X**
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	<u>Proceedings</u>		<u>Page</u>
7	WITNESSES	Direct Cross	Redirect Recross
9	Arch Carson, M.D.		
10	Ms. O'Dell	1258 --	1440, 1467 --
	Mr. Williams	-- 1317--	1459
11			
12			
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	1469
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1470

1 C E R T I F I C A T E

2
3 PURSUANT TO TITLE 28, U.S.C., SECTION 753, THE
4 FOLLOWING TRANSCRIPT IS CERTIFIED TO BE AN ACCURATE
5 TRANSCRIPTION OF MY STENOGRAPHIC NOTES IN THE
6 ABOVE-ENTITLED MATTER.

7
8 S/Vincent Russoniello
9 Vincent Russoniello, CCR
10 Certificate No. 675

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	11:30 [1] - 1315:2 12 [5] - 1327:4, 1356:4, 1372:19, 1465:23 1258 [1] - 1468:10 13 [1] - 1351:21 1317 [1] - 1468:10 137 [3] - 1267:14, 1431:10, 1436:24 139 [3] - 1412:5, 1412:9 14 [2] - 1350:19, 1410:20 143 [1] - 1343:2 1440,1467 [1] - 1468:10 1459 [1] - 1468:10 15 [5] - 1345:7, 1368:5, 1419:13, 1446:9, 1446:22 150 [3] - 1344:22, 1345:7, 1345:8 151 [1] - 1344:23 152 [1] - 1345:8 16 [6] - 1402:14, 1410:20, 1418:5, 1418:8, 1447:8, 1450:7 16-MD-2738(FLW)(LHG) [1] - 1256:2 168 [1] - 1351:21 169 [1] - 1364:11 17 [7] - 1364:11, 1402:2, 1402:13, 1402:14, 1428:10, 1447:8, 1447:10 174 [1] - 1369:2 175 [1] - 1366:18 18 [3] - 1266:14, 1351:21, 1440:25 180 [1] - 1320:12 181 [2] - 1361:24 18th [1] - 1425:9 1940s [1] - 1451:2 1948 [1] - 1298:5 1952 [1] - 1298:10 1961 [1] - 1279:24 1965 [1] - 1311:1 1979 [1] - 1280:2 198 [4] - 1402:2, 1402:13, 1441:21, 1441:22 1980s [1] - 1275:19 1981 [1] - 1272:7 1984 [4] - 1280:9, 1298:14, 1463:9, 1463:14 1985 [1] - 1324:2	1988 [4] - 1383:4, 1383:11, 1383:17 1989 [2] - 1430:8, 1447:19 199 [1] - 1442:5 1990 [1] - 1258:24 1992 [1] - 1277:21 1993 [1] - 1396:15 1995 [1] - 1397:24 1996 [3] - 1280:19, 1371:20, 1373:16 1997 [3] - 1280:11, 1429:11, 1447:18 1998 [2] - 1384:20, 1394:16 1999 [3] - 1303:20, 1304:9, 1392:7	1356:17, 1357:7 2013 [3] - 1278:3, 1412:3, 1412:6 2014 [1] - 1419:19 2016 [3] - 1312:23, 1416:25, 1419:18 2017 [1] - 1412:21 2018 [6] - 1277:25, 1421:13, 1428:17, 1431:5, 1431:8, 1431:11 2019 [3] - 1256:4, 1320:6, 1321:19 21 [4] - 1321:19, 1377:21, 1463:4, 1463:7 22 [5] - 1344:22, 1345:8, 1381:4, 1427:20, 1463:11 23 [6] - 1259:6, 1364:11, 1377:1, 1378:23, 1429:7, 1429:10 231 [1] - 1327:3 232 [1] - 1327:4 237 [1] - 1416:5 239 [1] - 1411:14 24 [5] - 1330:1, 1336:19, 1372:3, 1372:23, 1377:21 240 [2] - 1340:20, 1340:23 244 [1] - 1341:17 245 [1] - 1341:18 25 [2] - 1277:9, 1374:18 253 [1] - 1410:20 256 [1] - 1381:25 28 [1] - 1470:3 287 [1] - 1381:4 288 [1] - 1381:5 29 [2] - 1256:4, 1395:7 298 [2] - 1350:18, 1440:24 299 [3] - 1352:22, 1440:24, 1440:25 2A [1] - 1432:17 2B [10] - 1272:23, 1273:15, 1431:24, 1432:9, 1432:22, 1432:24, 1433:20, 1433:23, 1434:22, 1435:7	2
	1.0 [1] - 1417:3 1.10 [1] - 1430:8 1.10-to-1.54 [1] - 1429:14 1.25 [2] - 1277:8, 1422:22 1.3 [7] - 1406:13, 1406:16, 1407:5, 1407:9, 1411:21, 1429:13, 1454:3 1.73 [1] - 1430:10 1/2 [1] - 1373:25 10 [12] - 1296:9, 1333:16, 1340:5, 1341:13, 1361:24, 1369:2, 1373:25, 1386:3, 1396:11, 1413:18, 1460:14, 1461:16 100 [1] - 1302:9 105 [4] - 1301:14, 1301:17, 1392:7, 1392:24 109 [1] - 1419:13 11 [11] - 1366:18, 1374:12, 1375:2, 1412:24, 1413:10, 1413:19, 1418:5, 1418:7, 1422:15, 1441:1, 1461:15	1988 [4] - 1383:4, 1383:11, 1383:17 1989 [2] - 1430:8, 1447:19 199 [1] - 1442:5 1990 [1] - 1258:24 1992 [1] - 1277:21 1993 [1] - 1396:15 1995 [1] - 1397:24 1996 [3] - 1280:19, 1371:20, 1373:16 1997 [3] - 1280:11, 1429:11, 1447:18 1998 [2] - 1384:20, 1394:16 1999 [3] - 1303:20, 1304:9, 1392:7	2010 [17] - 1272:14, 1289:5, 1303:22, 1370:1, 1415:17, 1419:22, 1420:1, 1420:3, 1420:8, 1420:10, 1431:23, 1434:3, 1460:6, 1461:4, 1461:10, 1461:13, 1461:20 2012 [3] - 1272:25,	3
	3 [11] - 1264:18, 1321:17, 1369:2,			

<p>1372:16, 1372:17, 1372:18, 1373:8, 1377:1, 1378:23, 1381:21, 1435:15 3,000 [9] - 1406:24, 1407:17, 1407:21, 1407:24, 1408:7, 1408:13, 1408:23, 1409:10, 1409:20 30 [11] - 1259:20, 1275:17, 1288:22, 1340:11, 1341:1, 1395:8, 1406:10, 1408:7, 1408:18, 1409:19, 1410:4 300 [3] - 1341:13, 1374:20, 1374:21 309 [1] - 1357:9 31 [2] - 1431:17, 1435:14 319 [1] - 1295:18 322 [1] - 1378:23 325 [1] - 1333:15 326 [1] - 1333:16 349 [1] - 1377:1 350 [1] - 1377:1 354 [2] - 1329:24, 1336:18 355 [2] - 1330:1, 1336:19</p>	<p>507 [1] - 1465:22 508 [3] - 1394:24, 1395:21, 1452:13 516 [2] - 1321:14, 1321:23 517 [3] - 1431:2, 1431:18, 1435:12 53 [3] - 1385:17, 1386:16, 1388:7 56 [1] - 1445:20 58 [4] - 1427:20, 1429:7, 1463:2, 1463:7 588-9516 [1] - 1256:25</p>	<p>1403:14, 1403:22, 1418:5, 1433:10 943 [1] - 1422:19 95 [1] - 1429:5 99 [2] - 1422:23, 1454:20</p>	<p>A</p> <p>ability [6] - 1279:20, 1282:18, 1303:17, 1384:25, 1420:25, 1424:22 able [20] - 1276:10, 1281:23, 1282:23, 1289:16, 1292:14, 1312:18, 1312:20, 1333:21, 1333:25, 1334:3, 1334:10, 1335:13, 1352:12, 1353:2, 1355:22, 1361:14, 1378:19, 1422:10, 1422:11, 1450:23 abnormalities [1] - 1386:13 ABOVE [1] - 1470:6 ABOVE-ENTITLED [1] - 1470:6 absence [1] - 1425:2 absent [2] - 1316:9, 1458:8 absolutely [3] - 1322:5, 1443:22, 1447:17 absorbant [1] - 1263:1 abstract [6] - 1324:12, 1324:21, 1386:11, 1392:25, 1412:8, 1412:25 academic [1] - 1310:20 accelerated [1] - 1380:10 accept [1] - 1270:16 accepted [5] - 1270:19, 1332:13, 1458:13, 1458:16, 1458:18 access [1] - 1279:5 accomplished [1] - 1300:16 according [3] - 1328:15, 1331:14, 1345:14 accumulated [1] - 1312:23 accuracy [1] - 1393:19 ACCURATE [1] - 1470:4 accurate [6] - 1299:2,</p>
<p>4</p>	<p>7</p>	<p>7</p>	<p>absolutely [3] - 1322:5, 1443:22, 1447:17 absorbant [1] - 1263:1 abstract [6] - 1324:12, 1324:21, 1386:11, 1392:25, 1412:8, 1412:25 academic [1] - 1310:20 accelerated [1] - 1380:10 accept [1] - 1270:16 accepted [5] - 1270:19, 1332:13, 1458:13, 1458:16, 1458:18 access [1] - 1279:5 accomplished [1] - 1300:16 according [3] - 1328:15, 1331:14, 1345:14 accumulated [1] - 1312:23 accuracy [1] - 1393:19 ACCURATE [1] - 1470:4 accurate [6] - 1299:2,</p>
<p>4</p>	<p>8</p>	<p>8</p>	<p>8</p>
<p>5</p>	<p>9</p>	<p>9</p>	<p>9</p>

admitted [2] - 1449:21, 1456:1	1343:5, 1343:13, 1343:20, 1365:8, 1365:19, 1366:11, 1366:20	1277:18, 1277:19, 1278:1, 1326:10, 1418:25, 1419:2, 1421:13, 1422:7, 1425:2, 1425:3, 1448:1, ALLEN [1] - 1256:11	1446:22, 1463:4, 1463:18, 1463:19, 1465:3
adopted [1] - 1311:1		analysis [53] - 1262:6, 1275:21, 1276:4, 1276:25, 1277:17, 1310:4, 1310:16, 1310:23, 1312:22, 1315:20, 1347:16, 1365:25, 1368:12, 1373:24, 1376:1, 1409:5, 1409:13, 1409:14, 1411:19, 1412:6, 1413:1, 1413:13, 1413:21, 1420:2, 1420:5, 1421:16, 1421:23, 1422:18, 1422:21, 1422:23, 1424:1, 1424:11, 1431:8, 1436:1, 1436:2, 1437:21, 1444:19, 1444:23, 1445:5, 1446:6, 1446:11, 1446:21, 1453:13, 1453:15, 1453:24, 1456:25, 1462:7, 1462:18, 1463:3, 1465:13, 1466:14, 1466:17	annual [1] - 1287:16, 1358:23, 1359:7, 1380:8, 1383:19, 1390:12, 1390:15, 1394:22, 1398:9, 1434:8, 1444:7, 1464:21
advance [1] - 1436:9		answer [18] - 1269:2, 1304:24, 1304:25, 1308:19, 1309:17, 1318:8, 1347:8, 1348:1, 1352:3, 1353:5, 1360:11, 1361:14, 1363:3, 1390:17, 1402:14, 1407:17, 1410:9, 1445:16	
advancing [1] - 1332:15		ANSWER [37] - 1295:24, 1296:3, 1327:11, 1330:8, 1333:20, 1334:6, 1336:25, 1343:7, 1345:3, 1350:25, 1351:5, 1352:2, 1353:2, 1362:5, 1364:15, 1366:22, 1368:9, 1369:6, 1377:5, 1377:23, 1379:3, 1379:7, 1379:10, 1379:13, 1381:9, 1402:9, 1402:15, 1410:23, 1411:1, 1411:17, 1416:9, 1416:14, 1416:16, 1441:6, 1441:10, 1442:3, 1442:13	
aerosolized [1] - 1282:20		analytical [2] - 1264:8, 1347:14	answered [1] - 1451:23
affect [2] - 1346:2, 1346:16		analyze [1] - 1417:21	antioxidant [2] - 1289:9, 1289:19
affirmed [1] - 1465:6		analyzed [1] - 1419:15	anus [1] - 1399:14
affirming [1] - 1465:25		analyzing [1] - 1332:3	anytime [1] - 1424:19
afternoon [1] - 1352:8		anatomical [1] - 1398:14	anyway [2] - 1265:19, 1276:14
agency [1] - 1445:2		anatomy [4] - 1400:22, 1405:7, 1453:5, 1453:9	apologies [1] - 1442:23
agent [8] - 1287:6, 1288:4, 1289:25, 1439:5, 1439:8, 1439:13, 1439:15, 1451:1		ancillary [1] - 1378:4	apoptosis [2] - 1289:19, 1290:5
agents [2] - 1323:9, 1439:2		animal [22] - 1281:5, 1281:9, 1281:15, 1297:19, 1297:23, 1297:25, 1301:19, 1359:5, 1379:17, 1379:18, 1379:23, 1383:5, 1385:13, 1394:2, 1394:21, 1446:6, 1446:11,	Appeals [1] - 1467:16
ago [9] - 1303:4, 1320:6, 1327:23, 1335:3, 1391:23, 1407:12, 1407:16, 1419:10, 1466:18		appear [6] - 1266:18, 1294:19, 1299:22, 1299:24, 1301:9, 1385:9	appearing [1] - 1299:11
agree [26] - 1288:2, 1319:9, 1319:11, 1319:15, 1334:14, 1339:23, 1351:6, 1351:13, 1351:23, 1352:2, 1355:22, 1359:2, 1360:19, 1375:10, 1384:8, 1392:21, 1397:24, 1401:17, 1407:4, 1409:4, 1418:1, 1418:18, 1419:4, 1419:8, 1429:23, 1460:22		Appellate [1] - 1465:10	
agreed [2] - 1315:13, 1315:19			
ahead [2] - 1259:3, 1371:17			
air [5] - 1340:1, 1340:10, 1340:24, 1341:5, 1450:17			
airborne [1] - 1320:15			
airways [1] - 1285:8			
Akhtar [2] - 1289:5, 1289:14			
al [2] - 1382:4, 1429:11			
ALABAMA [2] - 1256:12, 1256:12			
alleged [8] - 1342:19,			

application [17] - 1282:11, 1283:2, 1310:11, 1317:20, 1328:25, 1330:10, 1332:24, 1336:1, 1341:24, 1349:25, 1394:19, 1399:17, 1399:19, 1399:21, 1400:14, 1401:23, 1456:20	1386:24, 1402:22, 1403:6, 1426:11, 1451:4 argue [1] - 1268:13 arguments [1] - 1313:4 arithmetic [2] - 1325:21, 1325:24 ARPS [1] - 1256:18 arrive [1] - 1334:22 arrived [1] - 1408:2 arriving [2] - 1314:22, 1390:1 arrows [1] - 1295:9 art [2] - 1404:19, 1404:23 article [15] - 1280:11, 1298:4, 1298:10, 1303:20, 1303:22, 1303:23, 1303:24, 1304:5, 1304:10, 1321:19, 1324:3, 1392:9, 1395:6, 1437:1	1347:7, 1347:18, 1348:6, 1349:7, 1349:12, 1349:14, 1349:15, 1349:18, 1349:24, 1350:4, 1350:10, 1350:12, 1350:21, 1350:23, 1351:6, 1351:8, 1351:9, 1351:12, 1351:17, 1351:24, 1352:13, 1352:15, 1352:24, 1354:13, 1355:8, 1355:11, 1355:15, 1356:1, 1356:17, 1357:13, 1357:15, 1357:20, 1434:9, 1441:14, 1443:24, 1444:2, 1448:20, 1455:16, 1455:23, 1457:22, 1458:25	1327:21 Associate [1] - 1258:21 associated [11] - 1277:4, 1291:11, 1304:1, 1334:19, 1348:23, 1384:15, 1412:10, 1413:14, 1439:2, 1439:19, 1453:25 associates [1] - 1357:19 association [51] - 1282:11, 1311:3, 1311:7, 1314:20, 1315:23, 1315:25, 1349:13, 1349:20, 1354:24, 1355:8, 1355:15, 1405:16, 1405:19, 1405:24, 1406:3, 1406:17, 1406:23, 1407:1, 1407:6, 1407:9, 1409:6, 1409:11, 1410:1, 1411:21, 1412:22, 1413:2, 1413:22, 1413:25, 1414:6, 1416:7, 1424:20, 1424:24, 1427:24, 1429:20, 1430:3, 1430:16, 1430:19, 1430:24, 1434:19, 1435:20, 1453:17, 1453:18, 1453:21, 1455:3, 1459:20, 1459:23, 1460:24, 1461:25, 1462:8, 1462:10
applies [2] - 1327:19, 1356:21	articles [3] - 1303:19, 1371:4, 1371:7	ASHCRAFT [1] - 1256:13	assume [2] - 1309:14, 1438:19
apply [1] - 1279:4	asbestiform [16] -	aside [2] - 1271:3, 1271:10	assuming [4] - 1408:23, 1409:12, 1430:4, 1430:5
applying [1] - 1427:8	1270:25, 1272:8, 1272:12, 1272:16, 1272:17, 1272:20, 1272:23, 1273:2, 1342:10, 1342:13, 1358:3, 1358:4, 1358:9, 1358:24, 1359:4, 1434:9	assertion [2] - 1408:13, 1412:21	assumption [4] - 1408:14, 1408:16, 1409:14, 1409:25
approach [8] - 1261:2, 1274:19, 1330:13, 1330:18, 1330:25, 1331:9, 1334:2, 1426:19	asbestos [87] - 1260:4, 1263:15, 1263:16, 1264:15, 1267:2, 1271:21, 1272:10, 1272:12, 1272:18, 1273:1, 1273:6, 1288:24, 1291:4, 1291:14, 1291:18, 1293:5, 1293:17, 1306:19, 1307:12, 1307:16, 1314:9, 1314:17, 1338:24, 1339:9, 1339:11, 1339:19, 1339:21, 1339:23, 1340:5, 1340:10, 1340:25, 1341:5, 1341:9, 1341:23, 1341:25, 1342:5, 1342:8, 1342:20, 1343:16, 1343:25, 1344:4, 1344:7, 1344:16, 1345:1, 1347:3, 1347:6	assessed [1] - 1312:9	assure [1] - 1261:20
approached [1] - 1261:1		assessing [2] - 1262:13, 1454:16	attack [1] - 1292:1
approaches [1] - 1325:16		assessment [37] - 1261:5, 1261:10, 1261:11, 1261:23, 1261:24, 1262:6, 1326:19, 1327:9, 1337:10, 1337:20, 1337:23, 1350:14, 1352:19, 1366:10, 1366:13, 1366:20, 1366:24, 1366:25, 1367:6, 1368:21, 1369:4, 1425:8, 1425:13, 1427:9, 1429:19, 1430:15, 1435:19, 1436:6, 1436:7, 1436:8, 1436:12, 1445:19, 1445:21, 1446:10, 1446:17, 1457:17, 1467:3	attempt [4] - 1333:17, 1341:22, 1343:15, 1417:14
appropriate [3] - 1447:22, 1465:13, 1466:14		assigning [1] - 1432:12	attempted [2] - 1312:20, 1342:19
Arch [4] - 1258:8, 1258:18, 1322:7, 1468:9		assist [4] - 1275:6, 1277:17, 1327:18	attempting [4] - 1276:18, 1292:5, 1292:12, 1388:10
ARCH [5] - 1258:10, 1317:4, 1354:6, 1415:5, 1440:15			attending [1] - 1377:7
area [24] - 1267:21, 1268:7, 1268:21, 1278:16, 1279:5, 1307:3, 1331:20, 1336:1, 1370:19, 1376:17, 1399:18, 1399:23, 1400:21, 1401:21, 1401:24, 1402:8, 1403:9, 1403:10, 1414:11, 1420:2, 1442:11, 1450:14			
areas [12] - 1300:19, 1304:19, 1305:9, 1320:12, 1320:16, 1332:9, 1386:8			

<p>attention [17] - 1273:8, 1305:10, 1333:15, 1340:20, 1343:2, 1350:18, 1355:2, 1355:3, 1357:9, 1372:16, 1379:25, 1381:22, 1383:3, 1412:24, 1437:1, 1441:19, 1445:18</p> <p>attribute [1] - 1388:10</p> <p>attributed [1] - 1388:4</p> <p>attributing [1] - 1388:17</p> <p>atypia [3] - 1386:9, 1386:13, 1386:23</p> <p>Austin [1] - 1310:25</p> <p>author [1] - 1270:10</p> <p>authored [1] - 1323:25</p> <p>authorities [1] - 1302:6</p> <p>authors [39] - 1278:10, 1281:11, 1281:21, 1298:4, 1301:11, 1313:2, 1324:3, 1326:9, 1327:14, 1369:20, 1372:2, 1372:23, 1373:2, 1373:10, 1383:17, 1383:24, 1384:2, 1384:20, 1385:24, 1386:7, 1387:21, 1389:13, 1391:19, 1392:18, 1392:22, 1396:3, 1396:14, 1398:17, 1412:15, 1413:6, 1413:20, 1413:25, 1422:7, 1431:7, 1435:13, 1435:19, 1437:21, 1445:4, 1446:21</p> <p>available [9] - 1274:22, 1316:6, 1346:24, 1369:6, 1425:13, 1427:23, 1446:3, 1446:18, 1457:6</p> <p>average [4] - 1275:16, 1325:21, 1325:24, 1408:19</p> <p>aware [19] - 1308:6, 1334:2, 1337:8, 1360:4, 1360:7, 1360:12, 1365:17, 1370:3, 1378:12, 1378:19, 1379:3, 1379:4, 1379:8, 1379:11, 1379:13,</p>	<p>1402:20, 1403:4, 1423:14, 1423:19</p> <p>awareness [1] - 1339:8</p> <p>axis [2] - 1306:4, 1306:7</p> <p style="text-align: center;">B</p> <p>Baby [14] - 1259:15, 1260:3, 1260:8, 1260:10, 1262:16, 1262:22, 1262:24, 1263:2, 1263:21, 1264:24, 1273:9, 1274:2, 1274:12, 1443:5</p> <p>baby [4] - 1263:4, 1274:10, 1326:20, 1327:9</p> <p>back-and-forth [1] - 1354:21</p> <p>backs [1] - 1383:19</p> <p>bad [1] - 1396:20</p> <p>balance [2] - 1290:1, 1388:12</p> <p>Balkwill [1] - 1303:24</p> <p>banned [1] - 1303:3</p> <p>bars [1] - 1398:11</p> <p>BART [1] - 1256:20</p> <p>Bart [1] - 1317:9</p> <p>base [1] - 1460:19</p> <p>based [26] - 1280:15, 1301:8, 1307:13, 1312:4, 1316:4, 1331:24, 1341:4, 1342:15, 1346:23, 1347:11, 1348:7, 1350:7, 1355:9, 1360:20, 1368:18, 1370:10, 1407:24, 1408:3, 1430:1, 1434:25, 1441:13, 1444:6, 1457:14, 1465:15, 1466:24, 1467:1</p> <p>baseline [1] - 1277:9</p> <p>basic [2] - 1318:10, 1405:7</p> <p>basis [12] - 1283:12, 1283:19, 1283:25, 1312:4, 1359:10, 1370:17, 1384:9, 1389:25, 1421:19, 1423:24, 1433:4, 1442:10</p>	<p>bathe [2] - 1442:13, 1442:14</p> <p>bathes [1] - 1401:25</p> <p>BE [1] - 1470:4</p> <p>BEASLEY [1] - 1256:11</p> <p>become [2] - 1286:10, 1286:12</p> <p>becomes [1] - 1283:7</p> <p>becoming [2] - 1284:22, 1436:9</p> <p>began [2] - 1262:7, 1262:13</p> <p>begin [1] - 1262:6</p> <p>beginning [6] - 1265:2, 1375:2, 1441:22, 1442:8, 1462:6, 1466:8</p> <p>begins [2] - 1374:10, 1374:17</p> <p>behalf [6] - 1256:14, 1256:22, 1257:6, 1258:10, 1268:23, 1445:11</p> <p>behave [1] - 1361:10</p> <p>behavior [1] - 1360:10</p> <p>BEISNER [1] - 1256:18</p> <p>belief [3] - 1330:15, 1384:18, 1423:24</p> <p>below [5] - 1266:19, 1331:10, 1331:16, 1413:11, 1417:3</p> <p>benefit [1] - 1262:8</p> <p>benzene [17] - 1319:21, 1319:24, 1320:6, 1320:11, 1320:15, 1320:21, 1320:24, 1321:4, 1321:5, 1321:20, 1322:2, 1322:12, 1322:18, 1322:20, 1322:22, 1322:23, 1356:24</p> <p>Berge [18] - 1412:21, 1413:6, 1413:25, 1414:5, 1420:11, 1421:16, 1421:22, 1422:12, 1423:22, 1448:2, 1461:9, 1461:13, 1461:14, 1461:16, 1461:18, 1462:1, 1462:3</p> <p>Berleson [4] - 1337:15, 1337:19, 1337:24, 1465:7</p> <p>better [4] - 1275:9,</p>	<p>1334:9, 1335:3, 1335:16</p> <p>between [51] - 1259:18, 1269:4, 1274:17, 1282:11, 1286:16, 1286:22, 1311:8, 1315:15, 1315:24, 1316:7, 1317:13, 1340:11, 1349:13, 1352:12, 1355:8, 1355:15, 1359:11, 1370:12, 1378:4, 1379:14, 1379:17, 1387:22, 1391:19, 1394:1, 1398:15, 1398:19, 1399:11, 1399:14, 1399:21, 1405:23, 1406:3, 1406:19, 1411:21, 1413:2, 1414:1, 1414:6, 1415:12, 1416:1, 1416:7, 1423:6, 1423:10, 1424:24, 1435:21, 1453:21, 1455:3, 1456:21, 1457:3, 1459:21, 1461:23, 1462:8, 1464:17</p> <p>beyond [2] - 1271:15, 1399:25</p> <p>bias [4] - 1435:3, 1435:9, 1435:22, 1436:13</p> <p>BIDDLE [1] - 1256:16</p> <p>billion [1] - 1320:12</p> <p>binder [4] - 1340:19, 1394:25, 1395:2, 1431:2</p> <p>biochemically [2] - 1287:9, 1287:12</p> <p>biologic [13] - 1296:10, 1312:12, 1312:25, 1335:7, 1375:17, 1378:14, 1379:1, 1379:5, 1379:9, 1379:12, 1448:4, 1459:1</p> <p>biological [11] - 1263:24, 1282:10, 1313:8, 1313:14, 1314:22, 1323:8, 1375:24, 1376:2, 1376:16, 1377:18, 1399:2</p> <p>biologically [4] - 1368:15, 1443:15, 1443:20, 1444:15</p>
---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

biologist [2] - 1377:16, 1377:22	bottled [1] - 1364:1	1295:6, 1297:9, 1300:11, 1301:18, 1309:19, 1317:7, 1327:6, 1332:22, 1346:14, 1348:4, 1354:9, 1371:18, 1415:8, 1428:16, 1440:18, 1443:1, 1459:12, 1466:21, 1467:14	1303:11, 1303:18, 1304:2, 1305:17, 1306:15, 1307:2, 1307:19, 1307:20, 1308:5, 1308:12, 1308:14, 1308:22, 1308:23, 1309:2, 1309:12, 1310:12, 1310:13, 1311:9, 1312:1, 1313:4, 1313:7, 1313:24, 1314:4, 1314:11, 1315:16, 1315:25, 1316:3, 1316:8, 1317:15, 1317:21, 1317:22, 1319:16, 1320:2, 1329:14, 1329:19, 1329:21, 1329:22, 1330:7, 1330:11, 1331:2, 1331:6, 1331:21, 1335:9, 1335:13, 1335:14, 1336:8, 1336:10, 1336:13, 1336:15, 1336:24, 1337:4, 1338:10, 1338:22, 1339:20, 1339:22, 1343:24, 1344:3, 1346:23, 1348:24, 1349:14, 1351:9, 1355:9, 1355:15, 1356:2, 1356:20, 1356:25, 1357:1, 1357:15, 1357:21, 1358:5, 1358:8, 1358:19, 1359:12, 1360:6, 1360:14, 1368:16, 1376:18, 1376:22, 1377:3, 1377:6, 1377:12, 1377:16, 1377:17, 1377:22, 1379:19, 1380:6, 1381:11, 1383:6, 1384:5, 1384:10, 1384:13, 1384:15, 1384:17, 1385:3, 1385:9, 1387:4, 1387:11, 1387:16, 1387:20, 1390:7, 1390:12, 1392:3, 1393:3, 1393:11, 1394:2, 1394:19, 1397:21, 1405:12, 1406:4, 1406:10,
biomarker [1] - 1290:4	bottom [11] - 1293:25, 1296:9, 1306:6, 1306:12, 1391:10, 1440:24, 1446:10, 1446:21, 1456:14, 1459:19, 1463:8		
biostatistician [4] - 1410:6, 1410:11, 1410:14, 1410:24	bound [1] - 1361:7		C
bit [4] - 1282:8, 1289:16, 1308:20, 1440:21	Bradford [12] - 1310:4, 1310:16, 1310:18, 1310:22, 1310:25, 1313:17, 1405:5, 1405:11, 1409:5, 1409:13, 1409:15, 1411:18		CA-125 [1] - 1290:4
blanks [1] - 1332:7	brand [1] - 1382:4		cage [1] - 1398:11
blew [1] - 1425:4	break [9] - 1276:3, 1276:6, 1287:8, 1315:5, 1316:11, 1353:8, 1354:11, 1414:14, 1415:9		calculate [3] - 1338:5, 1338:9, 1338:21
blocks [1] - 1313:22	breathe [1] - 1341:6		calculated [1] - 1336:3
blood [2] - 1364:19, 1364:25	breathing [2] - 1319:4, 1450:17		calculation [7] - 1421:5, 1421:7, 1423:15, 1458:7, 1458:20, 1465:17, 1465:18
bloodstream [2] - 1282:23, 1370:22	briefing [1] - 1308:1		calculations [2] - 1326:22, 1327:24
blow [1] - 1372:18	briefly [4] - 1272:4, 1279:14, 1310:16, 1449:24		CALIFORNIA [1] - 1256:20
board [3] - 1294:12, 1372:18, 1382:2	bring [2] - 1300:4, 1338:14		Canada [30] - 1282:7, 1316:1, 1316:4, 1425:7, 1425:8, 1425:21, 1426:10, 1426:15, 1427:14, 1429:19, 1430:15, 1430:23, 1435:14, 1436:7, 1436:14, 1436:21, 1438:1, 1438:3, 1444:24, 1444:25, 1445:2, 1445:3, 1445:12, 1445:19, 1447:7, 1457:2, 1457:15, 1463:3, 1463:17
bodies [5] - 1281:24, 1382:10, 1427:13, 1448:14, 1449:2	broad [2] - 1267:10, 1417:9		Canada's [1] - 1435:19
body [35] - 1285:12, 1292:2, 1303:5, 1305:7, 1350:12, 1350:24, 1353:1, 1363:23, 1369:14, 1370:5, 1370:23, 1373:12, 1373:22, 1374:23, 1375:1, 1381:13, 1382:5, 1383:16, 1391:4, 1391:15, 1391:20, 1395:16, 1399:18, 1399:22, 1401:2, 1401:5, 1401:9, 1404:25, 1417:22, 1417:25, 1434:25, 1447:23, 1448:16, 1450:24, 1465:18	BROWN [1] - 1256:22		Canadian [1] - 1427:8
body's [1] - 1384:25	build [3] - 1302:24, 1408:20, 1452:10		Cancer [3] - 1380:2, 1427:11, 1433:11
body-induced [1] - 1381:13	build-up [1] - 1302:24		cancer [181] - 1259:20, 1260:11, 1263:25, 1273:18, 1274:18, 1277:1, 1277:5, 1283:17, 1285:25, 1286:20, 1287:6, 1288:15, 1290:3, 1290:5, 1290:6, 1297:13, 1303:9,
bone [1] - 1399:15	bursas [1] - 1452:24		
book [7] - 1321:10, 1321:11, 1357:4, 1372:13, 1381:15, 1381:18, 1392:7	Buz'Zard [1] - 1289:1		
books [1] - 1321:10	BY [32] - 1256:12, 1256:14, 1256:16, 1256:18, 1256:20, 1256:22, 1257:6, 1258:15, 1260:19, 1269:25, 1272:3, 1276:21, 1284:11,		
Boorman [7] - 1394:23, 1395:8, 1395:10, 1396:13, 1397:1, 1397:24, 1464:2			
borrowed [1] - 1275:8			
bottle [1] - 1347:7			

1406:24, 1407:25, 1408:6, 1408:10, 1408:15, 1409:1, 1409:21, 1411:22, 1412:11, 1413:3, 1413:15, 1414:1, 1414:7, 1415:13, 1415:23, 1416:8, 1420:19, 1423:16, 1423:21, 1424:25, 1426:21, 1427:25, 1431:19, 1435:1, 1435:21, 1438:18, 1439:7, 1439:9, 1439:10, 1439:19, 1439:21, 1443:16, 1443:21, 1444:16, 1447:25, 1450:7, 1451:12, 1452:12, 1453:22, 1454:1, 1455:3, 1457:4, 1458:17, 1459:2, 1459:22, 1460:3, 1460:13, 1460:25, 1462:9, 1467:4, 1467:18 cancerous [1] - 1330:21 cancers [3] - 1338:1, 1439:1, 1451:7 cannot [9] - 1318:3, 1318:9, 1327:18, 1328:24, 1365:24, 1366:5, 1422:24, 1435:23, 1464:25 capability [2] - 1345:15, 1345:18 capable [2] - 1291:21, 1426:20 capacity [1] - 1382:11 carbon [2] - 1279:25, 1280:23 carcinogen [31] - 1267:1, 1272:23, 1272:24, 1273:3, 1273:5, 1273:6, 1273:16, 1286:2, 1286:25, 1287:1, 1287:2, 1305:20, 1307:6, 1307:22, 1307:23, 1309:4, 1314:25, 1315:7, 1315:9, 1319:12, 1319:16, 1319:21, 1319:24, 1432:22,	1433:1, 1435:7, 1437:16, 1439:5, 1439:6, 1439:14, 1444:2 carcinogenesis [19] - 1285:24, 1286:15, 1287:4, 1289:3, 1289:24, 1296:12, 1304:13, 1306:10, 1309:15, 1314:13, 1314:16, 1331:24, 1381:13, 1433:5, 1433:16, 1443:18, 1449:3, 1454:25, 1455:8 carcinogenetic [1] - 1465:2 carcinogenic [41] - 1260:9, 1267:4, 1274:8, 1286:4, 1291:2, 1291:5, 1291:16, 1292:22, 1293:2, 1305:14, 1305:16, 1305:18, 1305:20, 1306:5, 1306:18, 1307:24, 1308:8, 1308:10, 1308:11, 1308:18, 1309:13, 1339:2, 1359:19, 1359:20, 1359:24, 1360:10, 1362:9, 1362:11, 1367:12, 1382:4, 1382:11, 1404:4, 1432:8, 1432:9, 1432:12, 1432:13, 1433:4, 1435:16, 1438:11, 1438:13, 1439:15 carcinogenicity [13] - 1274:10, 1348:12, 1357:13, 1358:3, 1358:23, 1359:4, 1360:20, 1370:5, 1434:8, 1458:22, 1463:19, 1464:21, 1464:23 carcinogens [14] - 1273:15, 1285:24, 1305:12, 1305:14, 1306:25, 1308:16, 1308:17, 1310:2, 1360:2, 1382:14, 1382:19, 1382:22, 1432:17, 1444:13 carcinogenesis [1] -	1282:4 care [1] - 1417:10 Care [1] - 1257:6 carries [2] - 1341:18, 1463:9 carry [1] - 1397:9 carry-over [1] - 1397:9 Carson [82] - 1258:8, 1258:16, 1258:18, 1258:19, 1259:3, 1259:13, 1260:23, 1265:22, 1266:6, 1266:20, 1268:17, 1269:2, 1270:1, 1270:23, 1271:12, 1271:15, 1271:19, 1272:4, 1274:1, 1280:22, 1288:9, 1289:11, 1293:9, 1293:23, 1294:24, 1295:7, 1296:8, 1297:8, 1297:10, 1298:19, 1300:1, 1300:12, 1300:24, 1301:19, 1304:15, 1315:14, 1317:8, 1317:12, 1321:14, 1322:7, 1324:1, 1325:13, 1330:5, 1330:9, 1332:17, 1336:11, 1336:22, 1354:11, 1359:22, 1362:7, 1364:18, 1368:12, 1372:11, 1381:15, 1382:2, 1394:24, 1395:3, 1395:21, 1406:15, 1410:21, 1424:9, 1431:2, 1435:12, 1440:19, 1441:19, 1443:4, 1446:9, 1449:19, 1452:13, 1452:17, 1453:14, 1454:12, 1455:10, 1455:14, 1456:16, 1457:1, 1465:22, 1465:25, 1467:2, 1467:5, 1467:15, 1468:9 CARSON [5] - 1258:10, 1317:4, 1354:6, 1415:5, 1440:15 Carson's [9] - 1267:15, 1276:9, 1293:5, 1299:4,	1299:21, 1327:3, 1329:24, 1336:18, 1381:4 cascade [2] - 1283:15, 1294:24 case [43] - 1259:14, 1268:23, 1275:12, 1277:12, 1310:5, 1322:12, 1326:2, 1326:6, 1328:23, 1330:9, 1331:19, 1332:15, 1337:3, 1343:8, 1348:14, 1349:6, 1358:11, 1362:24, 1363:5, 1378:12, 1380:25, 1402:20, 1409:9, 1412:19, 1422:23, 1423:7, 1423:12, 1425:15, 1426:12, 1435:1, 1449:25, 1450:1, 1450:8, 1451:15, 1451:17, 1451:20, 1452:4, 1456:2, 1461:23, 1462:11, 1462:15, 1462:22 case-control [7] - 1275:12, 1423:7, 1435:1, 1461:23, 1462:11, 1462:15, 1462:22 cases [16] - 1323:23, 1326:14, 1350:7, 1357:2, 1361:11, 1366:4, 1383:15, 1407:25, 1408:8, 1409:21, 1422:19, 1422:20, 1423:16, 1423:19, 1423:21 casual [1] - 1400:5 casually [1] - 1400:4 catalysts [1] - 1443:11 catalytic [1] - 1273:21 catch [2] - 1326:4, 1394:6 categories [5] - 1325:22, 1326:12, 1432:16, 1432:21, 1433:23 Category [2] - 1432:17 category [5] - 1273:6, 1325:16, 1325:20, 1326:2, 1326:6
------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

causal [13] - 1315:25, 1316:7, 1355:8, 1409:6, 1410:1, 1439:9, 1440:1, 1445:21, 1457:3, 1457:6, 1459:23, 1460:23, 1461:24	1290:13, 1290:22, 1291:22, 1292:15, 1293:21, 1297:18, 1311:5, 1312:14, 1361:19, 1373:12, 1446:1	1385:6, 1387:11, 1387:16, 1387:25, 1388:2, 1388:5, 1388:24, 1389:11, 1390:18, 1391:24, 1397:19, 1415:19, 1465:2	1360:13, 1360:23, 1361:3, 1361:17, 1362:2, 1362:8, 1362:17, 1363:20, 1367:7, 1443:14
Causation [1] - 1444:21	cells [13] - 1273:20, 1289:8, 1289:10, 1290:1, 1290:5, 1290:6, 1292:1, 1292:4, 1296:3, 1296:14, 1380:9, 1380:10, 1391:5	channel [5] - 1279:4, 1399:11, 1400:19, 1400:22	chronic [25] - 1260:1, 1283:15, 1285:22, 1302:21, 1302:23, 1305:5, 1305:8, 1309:21, 1311:5, 1315:10, 1376:7, 1387:9, 1387:15, 1390:4, 1390:5, 1390:11, 1390:18, 1390:19, 1397:17, 1397:19, 1397:25, 1442:7, 1442:10, 1447:3, 1463:19
causation [14] - 1262:2, 1276:9, 1308:14, 1309:3, 1310:8, 1311:2, 1375:21, 1375:23, 1408:23, 1409:12, 1426:7, 1426:16, 1445:20, 1452:1	cellular [5] - 1273:24, 1285:23, 1290:23, 1296:18, 1386:23	characteristics [1] - 1263:2	Chronicle [1] - 1321:4
caused [2] - 1380:6, 1451:12	Center [1] - 1259:1	characterization [5] - 1261:13, 1405:23, 1406:22, 1429:23, 1442:21	cigarette [3] - 1458:12, 1458:15, 1458:16
causes [40] - 1287:6, 1288:1, 1290:11, 1298:1, 1301:21, 1302:3, 1303:10, 1305:4, 1308:23, 1310:13, 1311:23, 1316:3, 1317:20, 1329:14, 1329:19, 1330:6, 1336:13, 1336:23, 1343:24, 1344:3, 1346:22, 1356:25, 1357:15, 1358:4, 1378:13, 1379:18, 1379:19, 1380:8, 1380:14, 1383:6, 1390:4, 1390:11, 1390:17, 1393:11, 1397:25, 1405:12, 1443:21, 1446:2, 1447:3, 1458:16	center [2] - 1292:3, 1322:21	characterized [1] - 1391:22	Cincinnati [3] - 1259:8, 1270:5
causing [7] - 1303:8, 1307:19, 1331:2, 1361:11, 1426:20, 1446:7, 1459:2	central [3] - 1292:11, 1295:9, 1313:12	charge [1] - 1343:7	Circuit [1] - 1465:9
caveat [1] - 1267:17	certain [10] - 1263:7, 1264:3, 1293:11, 1308:16, 1314:18, 1342:8, 1342:10, 1346:12, 1347:5, 1357:20	chart [1] - 1428:4	circular [1] - 1410:3
cavities [1] - 1303:5	certainly [8] - 1268:9, 1270:14, 1294:23, 1297:2, 1312:14, 1360:8, 1410:14, 1448:16	check [2] - 1349:23, 1399:3	circulate [2] - 1282:24, 1370:22
cavity [3] - 1280:5, 1282:6, 1302:20	certainty [2] - 1371:12, 1371:15	checking [1] - 1271:5	circulation [1] - 1451:4
CCR [2] - 1256:24, 1470:8	Certificate [1] - 1470:9	chemical [5] - 1269:5, 1291:13, 1314:12, 1439:13, 1439:14	circumstances [3] - 1337:12, 1449:25, 1450:11
cell [25] - 1260:6, 1286:7, 1286:8, 1286:10, 1287:19, 1287:22, 1288:6, 1288:14, 1288:21, 1289:15, 1289:20, 1289:23, 1290:4,	CERTIFIED [1] - 1470:4	chemically [1] - 1314:10	citable [1] - 1390:10
	cervical [5] - 1402:7, 1403:10, 1403:17, 1442:1, 1442:11	chemicals [21] - 1263:10, 1274:2, 1274:4, 1274:5, 1274:9, 1306:24, 1322:20, 1323:9, 1324:22, 1325:5, 1362:23, 1362:25, 1363:4, 1367:12, 1367:22, 1367:25, 1368:7, 1368:22, 1369:5, 1439:2, 1458:21	cite [24] - 1369:14, 1369:21, 1370:12, 1371:5, 1374:22, 1374:25, 1379:22, 1380:12, 1380:18, 1381:7, 1383:4, 1390:7, 1390:16, 1398:25, 1400:25, 1405:8, 1412:2, 1412:20, 1414:5, 1418:15, 1418:18, 1418:20, 1418:25, 1449:13
	cervix [1] - 1379:5	chemotaxis [2] - 1296:14, 1380:9	cited [22] - 1284:3, 1284:7, 1341:20, 1374:22, 1378:17, 1380:21, 1385:12, 1389:20, 1390:13, 1395:8, 1395:13, 1398:22, 1404:25, 1405:25, 1418:22, 1419:9, 1420:11,
	chamber [1] - 1453:4	cherry [1] - 1418:21	
	chance [2] - 1435:22, 1436:13	cherry-picking [1] - 1418:21	
	change [17] - 1286:7, 1286:8, 1286:9, 1289:25, 1300:19, 1346:12, 1386:5, 1388:11, 1390:6, 1390:12, 1390:21, 1391:20, 1398:1, 1405:5, 1451:13, 1456:4, 1456:5	chest [3] - 1302:20, 1302:21, 1302:24	
	changed [1] - 1415:25	chose [2] - 1420:7, 1420:12	
	changes [14] - 1301:4,	chosen [1] - 1345:25	

1420:13, 1448:25, 1449:16, 1454:18 cites [5] - 1298:20, 1299:24, 1355:12, 1356:4, 1428:2 citing [3] - 1299:16, 1302:6, 1448:24 CIVIL [1] - 1256:2 clarify [1] - 1389:16 clarke [1] - 1279:14 clarke-Pearson [1] - 1279:14 CLARKSON [1] - 1256:7 classed [4] - 1273:3, 1273:13, 1273:14, 1434:22 classification [9] - 1356:21, 1431:19, 1431:22, 1432:10, 1432:11, 1432:13, 1432:23, 1433:20, 1433:23 classifications [1] - 1266:25 classified [1] - 1433:3 classifies [2] - 1319:24, 1356:19 classify [1] - 1432:20 classifying [1] - 1432:7 clean [2] - 1285:4, 1305:6 clear [4] - 1338:16, 1343:23, 1409:8, 1426:15 clearance [1] - 1284:24 clearly [6] - 1259:21, 1267:11, 1293:1, 1355:9, 1388:10, 1427:15 CLERK [9] - 1258:4, 1316:13, 1317:1, 1353:11, 1354:3, 1414:16, 1415:1, 1440:6, 1440:10 close [1] - 1454:7 closer [3] - 1375:23, 1402:7, 1442:2 co [2] - 1270:10, 1396:14 co-author [1] - 1270:10 co-authors [1] - 1396:14 cobalt [15] - 1263:9, 1273:12, 1273:15, 1308:2, 1308:3,	1309:21, 1360:5, 1360:13, 1360:24, 1361:3, 1362:8, 1362:17, 1363:20, 1367:7, 1443:14 coherence [2] - 1313:10, 1313:16 cohort [46] - 1275:13, 1275:20, 1275:22, 1276:5, 1276:25, 1277:3, 1277:12, 1315:23, 1355:10, 1414:10, 1415:10, 1415:11, 1416:6, 1416:7, 1416:17, 1417:21, 1418:3, 1418:10, 1418:13, 1418:24, 1420:2, 1420:18, 1420:23, 1421:8, 1421:19, 1421:24, 1422:8, 1422:17, 1422:21, 1422:24, 1423:6, 1423:10, 1423:25, 1424:1, 1424:2, 1424:3, 1424:6, 1424:7, 1449:6, 1449:8, 1459:20, 1460:17, 1461:24, 1462:16, 1462:17 cohorts [5] - 1417:24, 1423:17, 1424:11, 1424:24, 1449:5 colleagues [7] - 1262:12, 1270:4, 1280:9, 1281:18, 1289:22, 1325:2, 1411:10 collected [1] - 1350:2 College [1] - 1259:9 column [23] - 1301:16, 1324:6, 1324:25, 1325:12, 1357:10, 1372:21, 1373:3, 1373:9, 1381:22, 1382:18, 1386:17, 1386:21, 1388:8, 1391:1, 1393:24, 1397:8, 1413:19, 1428:24, 1429:2, 1429:4, 1430:3, 1430:19, 1431:23 combination [1] - 1263:6 combine [4] - 1333:10, 1334:7, 1334:16,	1334:20 combined [4] - 1360:5, 1360:13, 1441:3, 1441:11 coming [5] - 1267:22, 1269:20, 1294:4, 1314:6, 1452:9 commenting [1] - 1388:1 comments [1] - 1373:9 commercially [1] - 1346:24 commissioned [1] - 1445:3 Committee [1] - 1256:14 common [4] - 1277:6, 1302:11, 1306:8, 1393:4 companies' [1] - 1344:25 company [1] - 1344:24 company's [1] - 1344:14 compare [2] - 1264:13, 1341:22 compared [2] - 1364:20, 1365:2 compares [2] - 1350:11, 1350:23 comparing [1] - 1265:4 comparison [9] - 1278:12, 1285:19, 1288:13, 1288:24, 1298:8, 1352:12, 1352:23, 1353:3, 1411:10 compelling [9] - 1311:10, 1311:20, 1313:4, 1313:9, 1405:20, 1411:24, 1412:17, 1412:22, 1413:8 complete [4] - 1287:1, 1287:2, 1314:25, 1315:8 completed [1] - 1389:15 complex [1] - 1273:19 complexities [1] - 1301:2 complicated [1] - 1337:21 component [5] - 1263:15, 1293:19, 1295:5, 1306:8, 1444:3 components [13] - 1262:15, 1262:21, 1262:23, 1262:24, 1264:25, 1268:19, 1274:11, 1307:5,	1444:11, 1458:3, 1458:4, 1458:5, 1458:6 composition [3] - 1269:5, 1291:13, 1314:12 comprehensive [2] - 1445:25, 1457:7 comprised [1] - 1422:18 concentrated [1] - 1451:8 concentration [9] - 1322:6, 1340:4, 1340:10, 1341:11, 1389:2, 1389:9, 1401:20, 1402:6, 1441:25 concentrations [4] - 1320:11, 1340:7, 1340:25, 1389:7 concept [6] - 1314:24, 1319:17, 1421:4, 1457:12, 1457:13 concern [8] - 1271:23, 1320:17, 1320:21, 1320:25, 1321:6, 1322:3, 1322:14, 1396:6 concerned [4] - 1271:1, 1273:7, 1398:18, 1467:5 concerning [7] - 1317:10, 1327:15, 1331:15, 1349:6, 1437:7, 1460:2, 1460:24 concerns [1] - 1437:16 conclude [7] - 1362:7, 1387:14, 1416:17, 1421:24, 1424:1, 1424:11, 1457:2 concluded [12] - 1315:8, 1315:22, 1355:7, 1370:4, 1373:2, 1386:7, 1423:16, 1435:8, 1461:21, 1463:17, 1466:10, 1466:23 conclusion [23] - 1281:25, 1301:21, 1303:10, 1303:25, 1310:1, 1316:2, 1332:17, 1332:23, 1391:12, 1413:20, 1413:21, 1428:24, 1429:20, 1430:16, 1435:14, 1435:18, 1457:17, 1460:20,
---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

1461:13, 1461:17, 1462:1, 1462:12, 1467:1 conclusions [15] - 1275:1, 1313:10, 1313:20, 1314:23, 1334:11, 1334:22, 1367:18, 1374:2, 1374:10, 1378:20, 1391:10, 1422:1, 1423:6, 1424:13, 1424:14 concurred [1] - 1282:13 condition [1] - 1422:9 conduct [5] - 1337:10, 1337:19, 1366:10, 1367:6, 1467:2 conducted [6] - 1345:24, 1404:12, 1404:16, 1424:8, 1455:4, 1465:11 conducting [3] - 1337:22, 1409:4, 1410:16 confidence [7] - 1429:5, 1429:13, 1429:16, 1430:1, 1430:10, 1430:13, 1430:21 confines [1] - 1290:13 confirm [1] - 1313:20 confirmation [2] - 1315:23, 1459:20 confounding [5] - 1311:25, 1435:3, 1435:9, 1435:22, 1436:13 conjecture [1] - 1466:25 connect [1] - 1302:23 connecting [1] - 1467:17 connection [8] - 1303:18, 1311:13, 1349:5, 1359:11, 1370:12, 1371:3, 1379:17, 1440:1 conservative [1] - 1322:2 consider [27] - 1261:15, 1261:17, 1261:21, 1267:16, 1277:13, 1281:5, 1287:17, 1287:22, 1297:23, 1304:4, 1311:12, 1312:12, 1314:5, 1316:1, 1368:13, 1388:16, 1398:13	1406:16, 1407:5, 1407:9, 1411:7, 1411:8, 1411:15, 1455:21, 1457:23, 1460:6, 1460:8 considerably [1] - 1362:19 consideration [10] - 1311:9, 1311:20, 1312:5, 1313:1, 1313:16, 1313:18, 1398:18, 1419:5, 1427:17, 1449:15 considerations [1] - 1310:24 considered [21] - 1271:19, 1272:13, 1272:22, 1273:1, 1273:5, 1275:3, 1288:6, 1290:10, 1301:20, 1303:14, 1309:25, 1313:11, 1315:21, 1356:10, 1375:7, 1388:13, 1390:1, 1392:22, 1407:15, 1437:22, 1449:6 considering [1] - 1333:21 consistency [6] - 1311:11, 1311:15, 1311:19, 1314:21, 1455:2, 1456:20 consistent [10] - 1259:18, 1275:18, 1278:15, 1290:17, 1290:19, 1397:10, 1409:17, 1435:2, 1436:3, 1455:9 consists [1] - 1293:6 constituents [5] - 1266:16, 1296:12, 1360:8, 1404:2, 1444:8 consult [1] - 1377:17 Consumer [1] - 1343:6 contact [1] - 1273:21 contacts [1] - 1260:2 contain [14] - 1260:4, 1274:7, 1306:24, 1342:5, 1342:8, 1342:10, 1342:13, 1344:4, 1347:3, 1348:6, 1444:13, 1445:22, 1445:25, 1446:5 contained [14] -	1264:19, 1273:9, 1274:2, 1298:20, 1347:5, 1348:19, 1349:1, 1366:11, 1366:21, 1367:4, 1418:15, 1443:4, 1444:9, 1450:15 container [1] - 1263:4 containing [11] - 1272:16, 1272:22, 1273:2, 1343:25, 1358:3, 1358:4, 1358:9, 1358:23, 1359:4, 1434:8 contains [1] - 1327:1 contaminant [2] - 1342:20, 1343:5 contaminants [8] - 1343:13, 1343:20, 1348:11, 1348:18, 1365:8, 1365:14, 1365:19, 1366:8 contamination [2] - 1338:25, 1339:1 contend [1] - 1368:15 content [2] - 1306:20, 1365:22 contents [1] - 1305:17 context [13] - 1324:20, 1326:4, 1338:13, 1338:14, 1339:12, 1339:14, 1339:16, 1376:23, 1433:22, 1437:23, 1438:10, 1458:15 continually [1] - 1305:6 continue [4] - 1259:3, 1263:18, 1289:13, 1291:9 continued [2] - 1354:8, 1415:7 Continued [3] - 1316:15, 1353:13, 1414:18 continues [4] - 1301:15, 1428:7, 1428:10, 1428:14 Continuing [1] - 1461:17 continuous [1] - 1296:18 contradict [1] - 1418:20 contrary [1] - 1419:5 contrast [1] - 1451:1 contribute [7] - 1297:15, 1307:5, 1307:8, 1367:12, 1443:19,	1458:22, 1459:1 contributed [5] - 1368:11, 1417:19, 1418:24, 1438:2, 1449:17 contribution [4] - 1274:9, 1285:18, 1309:2, 1441:11 control [9] - 1275:12, 1277:12, 1422:23, 1423:7, 1435:1, 1461:23, 1462:11, 1462:15, 1462:22 controls [1] - 1372:20 Cook [1] - 1268:22 coordinated [1] - 1360:8 copy [2] - 1260:13, 1260:14 corner [1] - 1301:15 cornstarch [1] - 1280:24 corporate [1] - 1455:20 Correct [134] - 1284:14, 1317:16, 1318:1, 1318:12, 1319:7, 1319:19, 1320:3, 1322:22, 1323:10, 1323:22, 1326:17, 1327:12, 1328:16, 1329:14, 1329:19, 1338:11, 1339:2, 1339:15, 1342:1, 1342:9, 1342:21, 1343:9, 1345:5, 1345:9, 1347:13, 1348:24, 1349:8, 1350:13, 1352:4, 1355:12, 1356:8, 1357:1, 1357:7, 1357:23, 1358:12, 1358:17, 1359:20, 1360:17, 1360:25, 1361:17, 1362:13, 1362:24, 1363:5, 1367:1, 1369:16, 1370:6, 1371:21, 1371:25, 1372:4, 1375:2, 1376:5, 1377:12, 1377:25, 1379:6, 1380:24, 1383:22, 1384:3, 1384:18, 1385:7, 1386:9, 1386:14, 1387:4, 1387:12, 1391:7, 1391:25,
--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

1392:3, 1392:12, 1392:19, 1393:6, 1393:12, 1393:20, 1394:5, 1396:16, 1396:20, 1397:6, 1398:23, 1402:11, 1402:17, 1405:9, 1405:16, 1407:6, 1407:10, 1409:2, 1410:2, 1411:3, 1411:22, 1412:18, 1412:22, 1415:14, 1415:24, 1416:23, 1417:18, 1419:16, 1419:20, 1419:23, 1420:10, 1421:2, 1421:10, 1422:1, 1425:14, 1425:25, 1426:17, 1426:21, 1427:4, 1427:11, 1429:14, 1429:17, 1430:21, 1431:12, 1431:14, 1431:24, 1432:25, 1434:10, 1434:14, 1435:16, 1436:3, 1437:22, 1439:3, 1439:16, 1439:21, 1448:17, 1459:15, 1459:24, 1460:3, 1460:9, 1461:1, 1461:6, 1462:1, 1462:24, 1463:22, 1463:24, 1464:13, 1464:16, 1464:22	1348:9, 1348:25, 1349:4, 1350:24, 1355:1, 1355:13, 1356:22, 1357:2, 1358:13, 1359:21, 1360:3, 1360:18, 1362:3, 1363:6, 1363:15, 1369:17, 1369:20, 1372:1, 1372:5, 1372:8, 1373:1, 1373:20, 1374:15, 1375:3, 1375:18, 1375:19, 1376:14, 1377:4, 1377:10, 1377:23, 1379:2, 1379:7, 1380:17, 1381:11, 1381:12, 1383:15, 1384:1, 1384:6, 1385:5, 1386:2, 1386:5, 1386:6, 1386:10, 1386:15, 1387:8, 1387:13, 1387:17, 1390:23, 1392:1, 1392:4, 1392:10, 1392:17, 1393:7, 1394:10, 1395:15, 1396:21, 1397:5, 1397:7, 1397:14, 1401:16, 1401:22, 1403:8, 1404:11, 1405:10, 1405:14, 1405:17, 1406:13, 1406:14, 1406:18, 1408:12, 1409:3, 1409:7, 1410:22, 1410:23, 1412:1, 1412:6, 1412:13, 1412:14, 1412:19, 1415:15, 1416:8, 1416:13, 1416:16, 1416:24, 1417:2, 1417:5, 1417:7, 1417:23, 1418:17, 1419:17, 1419:21, 1419:24, 1420:17, 1420:22, 1424:19, 1426:4, 1426:18, 1428:1, 1429:15, 1429:18, 1430:9, 1430:12, 1431:25, 1432:14, 1432:15, 1432:19, 1434:11, 1434:15, 1434:18, 1435:10, 1439:4,	1439:7, 1439:11, 1439:17, 1440:2, 1445:6, 1446:19, 1446:20, 1446:24, 1457:19, 1458:23, 1459:25, 1460:7, 1461:2, 1461:11, 1462:5, 1462:25, 1463:13, 1463:16, 1464:7, 1465:7, 1465:8, 1466:5, 1466:6, 1466:9, 1466:11 correctional [1] - 1450:2 correctly [6] - 1322:10, 1357:17, 1357:18, 1382:8, 1398:16, 1437:11 correlate [2] - 1355:14, 1373:5 correlation [1] - 1379:14 cosmetic [8] - 1280:20, 1341:24, 1351:24, 1361:4, 1361:17, 1361:19, 1362:2, 1362:8 Cottreau [2] - 1392:6, 1393:10 Council [1] - 1257:6 counsel [3] - 1343:12, 1431:6, 1463:2 count [1] - 1420:5 couple [6] - 1266:15, 1267:25, 1269:23, 1289:14, 1316:12, 1451:22 course [9] - 1262:25, 1351:11, 1388:19, 1394:15, 1401:6, 1439:12, 1444:13, 1446:17, 1460:14 COURT [102] - 1256:1, 1256:25, 1258:5, 1259:11, 1260:15, 1265:6, 1265:13, 1265:24, 1266:2, 1266:11, 1267:6, 1267:20, 1267:25, 1268:12, 1268:25, 1269:6, 1269:9, 1269:13, 1269:15, 1269:18, 1269:24, 1270:11, 1271:3, 1271:9, 1271:24, 1276:3, 1276:12,	1276:19, 1277:22, 1283:19, 1283:22, 1283:25, 1284:6, 1294:1, 1294:9, 1294:19, 1294:22, 1295:18, 1296:22, 1298:25, 1299:7, 1299:15, 1300:3, 1301:13, 1308:19, 1309:5, 1309:10, 1309:17, 1315:1, 1315:4, 1316:11, 1317:2, 1327:5, 1329:25, 1332:21, 1333:14, 1336:17, 1344:21, 1346:6, 1347:22, 1347:25, 1350:17, 1351:20, 1352:9, 1352:21, 1353:9, 1354:4, 1361:23, 1364:10, 1366:17, 1368:4, 1369:1, 1370:10, 1370:16, 1370:24, 1371:2, 1371:10, 1371:17, 1376:25, 1377:20, 1378:22, 1381:3, 1410:9, 1410:19, 1411:13, 1414:11, 1414:13, 1415:2, 1416:4, 1428:13, 1440:5, 1440:11, 1442:24, 1445:16, 1454:8, 1456:9, 1459:6, 1459:9, 1462:20, 1466:16, 1467:11, 1467:21 court [6] - 1258:3, 1337:14, 1427:3, 1440:9, 1466:17, 1467:23 Court [19] - 1258:7, 1258:20, 1259:13, 1268:18, 1271:1, 1272:5, 1305:25, 1310:22, 1327:18, 1327:21, 1337:18, 1464:25, 1465:10, 1465:14, 1465:15, 1466:10, 1466:23, 1467:16 COURTHOUSE [1] - 1256:7
-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

<p>courts [2] - 1332:12, 1332:18 covering [2] - 1386:8, 1398:10 Cramer [2] - 1284:12, 1312:23 create [2] - 1273:22, 1442:10 creating [1] - 1296:24 credible [2] - 1375:24, 1467:17 Criminal [1] - 1337:15 criticizing [1] - 1421:19 Cross [1] - 1468:7 cross [4] - 1300:5, 1429:16, 1444:20, 1466:8 CROSS [3] - 1317:6, 1354:8, 1415:7 cross-examination [2] - 1444:20, 1466:8 CROSS-EXAMINATION [3] - 1317:6, 1354:8, 1415:7 crosses [2] - 1430:13, 1430:21 Crowley's [2] - 1367:18, 1368:24 CRR [1] - 1256:24 crude [1] - 1367:17 crystal [3] - 1361:7, 1361:10, 1364:7 crystals [3] - 1263:8, 1366:14, 1367:4 cubic [3] - 1340:5, 1340:11, 1341:1 culture [2] - 1287:20, 1290:13 cultures [1] - 1296:4 cumulative [2] - 1276:1, 1276:8 current [2] - 1331:14, 1427:15 cut [2] - 1300:22, 1398:22 cytokines [2] - 1290:16, 1296:15 cytoplasmic [1] - 1386:9</p>	<p>damage [6] - 1273:24, 1289:7, 1296:8, 1297:11, 1315:10, 1361:11 damaging [1] - 1298:12 Daniel [4] - 1431:7, 1431:14, 1445:8 data [32] - 1277:20, 1312:23, 1316:6, 1326:8, 1332:9, 1344:13, 1350:2, 1392:11, 1392:14, 1393:19, 1394:2, 1394:15, 1398:13, 1419:1, 1420:3, 1420:4, 1435:19, 1438:5, 1447:15, 1447:19, 1453:14, 1453:17, 1453:20, 1457:6, 1457:8, 1460:2, 1460:23, 1460:24, 1461:10, 1461:12, 1461:19, 1462:13 date [1] - 1425:10 DAUBERT [1] - 1256:4 Daubert [5] - 1308:1, 1337:14, 1338:19, 1345:14, 1449:20 day-to-day [1] - 1319:18 days [1] - 1320:10 de [1] - 1333:18 deadly [1] - 1277:6 deal [5] - 1265:13, 1266:3, 1297:2, 1319:17, 1355:16 dealing [3] - 1270:14, 1442:7, 1454:22 deals [1] - 1414:10 dealt [1] - 1354:18 Dear [3] - 1320:7, 1320:13, 1320:16 death [2] - 1289:20, 1450:9 deaths [1] - 1406:24 decade [1] - 1450:6 decades [1] - 1283:12 December [1] - 1425:9 decision [5] - 1338:15, 1449:20, 1465:20, 1467:16 deck [2] - 1260:14, 1264:19 decrease [1] - 1290:5</p>	<p>deep [2] - 1285:6, 1285:11 deeper [2] - 1274:14, 1279:5 Defendant [2] - 1256:22, 1257:6 defense [1] - 1366:1 defer [2] - 1342:23, 1343:7 define [6] - 1295:1, 1295:7, 1311:22, 1331:4, 1334:8, 1335:16 definition [1] - 1335:3 degree [4] - 1332:17, 1371:12, 1371:15, 1466:12 dehydrogenase [1] - 1289:7 demonstrate [2] - 1276:24, 1305:23 demonstrated [1] - 1309:20 demonstrates [1] - 1269:7 demonstrating [1] - 1270:17 demonstration [1] - 1425:17 demonstrative [2] - 1265:3, 1306:1 demonstratives [1] - 1292:24 deny [3] - 1321:3, 1322:24, 1323:1 Department [2] - 1337:15, 1411:5 depended [1] - 1382:5 dependent [1] - 1343:24 depict [1] - 1305:23 depicted [3] - 1272:5, 1295:4, 1295:8 depicting [2] - 1293:24, 1294:4 depiction [3] - 1269:10, 1299:2, 1299:3 depicts [5] - 1262:23, 1270:24, 1275:10, 1295:10, 1306:3 deposit [2] - 1264:6 deposited [3] - 1285:2, 1302:16, 1399:25 depositing [1] - 1303:5 deposition [34] -</p>	<p>1264:22, 1266:22, 1267:3, 1267:15, 1293:15, 1294:10, 1294:16, 1294:25, 1295:18, 1300:2, 1304:17, 1327:3, 1329:24, 1333:16, 1334:17, 1335:15, 1336:19, 1337:6, 1343:3, 1344:22, 1350:19, 1352:10, 1352:22, 1353:5, 1381:4, 1398:8, 1423:11, 1424:5, 1440:20, 1441:20, 1442:17, 1443:3, 1446:15 deposits [3] - 1347:16, 1363:10, 1455:24 DEPUTY [9] - 1258:4, 1316:13, 1317:1, 1353:11, 1354:3, 1414:16, 1415:1, 1440:6, 1440:10 describe [9] - 1260:23, 1279:15, 1284:23, 1284:24, 1291:7, 1359:19, 1373:22, 1375:11, 1404:9 described [8] - 1265:1, 1265:23, 1305:2, 1313:9, 1314:21, 1375:8, 1426:6, 1442:8 describes [2] - 1356:25, 1435:14 describing [3] - 1293:3, 1294:24, 1305:23 description [2] - 1284:21, 1416:10 design [3] - 1424:6, 1430:5, 1460:18 designated [3] - 1269:16, 1365:17, 1366:6 Designated [1] - 1259:1 designating [1] - 1435:7 designation [1] - 1431:24 designations [1] - 1432:1 designed [3] - 1285:3, 1287:10, 1322:19 designs [1] - 1455:4</p>
D	D.C [2] - 1256:18, 1257:6 daily [3] - 1326:20, 1327:10, 1341:25		

desirable [1] - 1263:2	diagnoses [1] - 1408:6	Director [1] - 1258:25	1284:17, 1286:23,
despite [2] - 1301:2, 1337:1	diagram [1] - 1454:25	director [1] - 1259:4	1294:18, 1338:24,
detail [4] - 1293:8, 1338:14, 1338:17, 1408:17	died [1] - 1450:7	dis [1] - 1295:14	1361:2, 1415:9,
detect [11] - 1322:19, 1420:15, 1420:20, 1421:1, 1421:9, 1422:11, 1422:21, 1424:15, 1424:19, 1424:22, 1425:1	differ [1] - 1360:19	dis-regulates [1] - 1295:14	1459:13, 1464:25
detected [3] - 1361:4, 1373:4, 1420:16	difference [7] - 1267:18, 1269:3, 1270:12, 1420:20, 1421:1, 1421:9, 1426:5	disagree [5] - 1265:15, 1319:14, 1331:3, 1359:2, 1461:3	Doctor [20] - 1260:20, 1283:20, 1284:23,
detection [1] - 1394:3	differences [4] - 1264:14, 1387:22, 1398:15, 1398:18	disclosed [1] - 1271:7	1286:18, 1295:1,
determination [1] - 1315:6	different [37] - 1267:23, 1268:18, 1286:1, 1289:23, 1307:9, 1314:13, 1314:14, 1325:22, 1332:6, 1351:7, 1351:11, 1351:13, 1351:14, 1351:15, 1351:16, 1351:25, 1357:14, 1360:24, 1361:18, 1364:24, 1365:6, 1366:23, 1375:7, 1411:24, 1416:1, 1425:25, 1439:1, 1439:2, 1439:15, 1451:24, 1453:8, 1460:18, 1460:19, 1462:13, 1463:1	discounted [1] - 1281:15	1296:1, 1310:15, 1332:11, 1332:24,
determine [13] - 1323:15, 1323:18, 1323:21, 1328:10, 1335:18, 1344:7, 1359:9, 1359:11, 1377:12, 1409:5, 1409:20, 1424:3, 1429:25	differently [2] - 1289:16, 1361:10	discuss [5] - 1260:21, 1264:21, 1387:22, 1393:15, 1393:21	1351:6, 1366:5, 1377:24, 1385:19,
determined [20] - 1272:10, 1275:13, 1281:11, 1311:4, 1311:6, 1311:19, 1316:4, 1325:23, 1329:12, 1329:17, 1330:5, 1336:6, 1336:12, 1336:14, 1336:22, 1367:3, 1450:12, 1450:21, 1465:15	difficult [5] - 1328:2, 1328:10, 1328:13, 1345:20, 1453:11	discussed [9] - 1264:10, 1265:12, 1284:13, 1313:2, 1342:11, 1402:23, 1424:4, 1424:5, 1464:8	1389:5, 1411:2, 1424:23, 1428:18,
determining [2] - 1287:5, 1327:18	diffraction [1] - 1272:10	discusses [1] - 1266:9	1441:17, 1462:14, 1466:22
develop [4] - 1287:25, 1318:7, 1323:15, 1323:18	digestive [1] - 1285:12	discussing [3] - 1265:11, 1392:14, 1413:11	Doctor's [1] - 1292:18
developed [6] - 1274:17, 1285:3, 1285:18, 1302:14, 1450:7, 1451:6	Direct [1] - 1468:7	discussion [11] - 1266:8, 1266:11, 1267:8, 1267:11, 1293:4, 1293:6, 1294:7, 1294:11, 1294:13, 1294:17, 1354:16	document [8] - 1342:12, 1434:5, 1436:4, 1436:11, 1436:20, 1445:1, 1445:22, 1447:7
developing [2] - 1330:11, 1413:15	DIRECT [1] - 1258:14	disease [6] - 1277:6, 1311:24, 1375:25, 1383:13, 1393:5, 1409:1	documents [10] - 1262:9, 1264:11, 1342:11, 1343:1, 1344:19, 1345:22, 1366:3, 1369:25, 1455:20
development [9] - 1304:12, 1311:8, 1317:15, 1387:19, 1388:5, 1395:19, 1414:7, 1454:1, 1464:24	direct [19] - 1282:4, 1291:21, 1325:13, 1333:15, 1340:20, 1343:2, 1350:18, 1355:2, 1355:3, 1357:9, 1372:16, 1379:14, 1379:24, 1381:22, 1383:3, 1388:12, 1390:25, 1412:24, 1437:1	disabilities [2] - 1311:24, 1385:1	done [26] - 1276:15, 1279:19, 1281:10, 1281:17, 1289:12, 1291:4, 1302:23, 1313:6, 1327:23, 1328:1, 1337:2, 1344:9, 1346:23, 1347:13, 1348:1, 1348:8, 1362:12, 1368:12, 1369:18, 1389:5, 1408:19, 1436:21, 1438:7, 1441:7, 1465:4, 1466:19
device [1] - 1450:25	directed [1] - 1463:3	display [1] - 1462:6	donned [1] - 1302:13
diagnosed [1] - 1408:9	direction [1] - 1456:21	dispute [4] - 1265:9, 1344:17, 1345:2, 1345:4	dose [71] - 1288:15, 1290:17, 1306:4, 1307:19, 1307:23, 1312:13, 1312:15, 1312:19, 1312:20, 1318:11, 1318:19, 1318:20, 1318:23, 1319:9, 1324:16, 1326:11, 1326:15, 1327:15, 1328:7,

1328:10, 1328:15, 1328:17, 1328:21, 1329:3, 1331:5, 1331:22, 1331:23, 1332:4, 1332:10, 1332:24, 1333:1, 1333:7, 1333:9, 1333:11, 1334:6, 1334:15, 1334:18, 1334:25, 1335:21, 1337:10, 1337:20, 1337:22, 1350:4, 1350:9, 1350:21, 1351:4, 1362:15, 1367:6, 1368:13, 1368:21, 1369:4, 1369:7, 1394:12, 1451:20, 1454:13, 1454:14, 1457:21, 1457:23, 1458:2, 1458:7, 1458:9, 1458:20, 1465:13, 1467:2 dose-response [14] - 1312:13, 1312:15, 1312:19, 1312:20, 1318:19, 1331:5, 1333:1, 1367:6, 1368:21, 1369:4, 1369:7, 1394:12, 1454:13, 1454:14 doses [7] - 1290:19, 1323:18, 1334:12, 1334:19, 1334:20, 1350:7, 1350:15 dosing [1] - 1458:14 double [1] - 1420:5 double-count [1] - 1420:5 doubt [1] - 1311:14 down [14] - 1276:4, 1276:6, 1287:9, 1307:3, 1316:12, 1388:20, 1391:10, 1393:25, 1394:13, 1401:8, 1412:9, 1427:14, 1430:7, 1437:4 dr [1] - 1260:23 Dr [114] - 1258:8, 1258:16, 1258:19, 1259:3, 1259:13, 1265:5, 1265:22, 1266:6, 1266:19,	1266:20, 1267:1, 1267:15, 1268:17, 1268:22, 1269:2, 1269:17, 1269:19, 1270:1, 1270:4, 1270:23, 1271:12, 1271:14, 1271:15, 1271:17, 1271:18, 1271:19, 1272:4, 1274:1, 1275:5, 1275:9, 1276:1, 1276:9, 1279:14, 1280:22, 1288:9, 1289:11, 1293:5, 1293:9, 1293:23, 1294:24, 1295:7, 1296:7, 1297:8, 1297:10, 1298:19, 1299:4, 1299:21, 1300:1, 1300:12, 1300:24, 1301:19, 1304:15, 1315:14, 1317:8, 1317:12, 1322:7, 1327:3, 1329:24, 1330:5, 1330:9, 1332:17, 1336:11, 1336:18, 1336:22, 1345:13, 1345:23, 1345:24, 1346:2, 1346:10, 1346:15, 1346:17, 1354:11, 1359:22, 1362:7, 1364:18, 1365:13, 1367:18, 1368:12, 1368:23, 1372:11, 1381:4, 1381:15, 1382:2, 1395:3, 1396:13, 1406:15, 1410:21, 1421:15, 1423:11, 1423:15, 1424:9, 1435:13, 1435:18, 1436:25, 1440:19, 1441:19, 1443:4, 1445:8, 1446:9, 1449:19, 1452:17, 1453:14, 1454:12, 1455:10, 1455:14, 1455:15, 1456:1, 1456:16, 1457:1, 1465:25, 1467:2, 1467:5, 1467:15 draft [9] - 1425:8, 1425:13, 1427:9,	1429:19, 1430:15, 1435:19, 1436:6, 1436:7, 1436:12 drainage [1] - 1285:17 draw [5] - 1378:3, 1378:20, 1379:14, 1399:21, 1437:25 drawn [1] - 1313:11 drew [1] - 1391:19 drink [1] - 1318:25 DRINKER [1] - 1256:16 drinking [4] - 1340:1, 1341:9, 1341:11, 1364:1 Drs [1] - 1393:10 Drug [1] - 1282:2 drugs [2] - 1314:3, 1323:9 due [3] - 1273:24, 1283:17, 1291:12 duly [1] - 1258:11 duration [6] - 1328:14, 1328:20, 1333:12, 1368:13, 1457:24, 1458:11 during [10] - 1259:24, 1262:10, 1282:21, 1302:16, 1303:5, 1328:4, 1333:22, 1350:11, 1350:22, 1454:19 dust [4] - 1259:24, 1282:21, 1337:25, 1370:21 dusted [1] - 1302:12	1318:20, 1318:21, 1320:17, 1320:20, 1320:21, 1321:7, 1339:2, 1344:18, 1348:10, 1364:22, 1391:14, 1403:19, 1404:4, 1407:18, 1407:22, 1420:15, 1422:11, 1424:14, 1425:18, 1443:12, 1444:4, 1453:7, 1456:21, 1456:23, 1457:6, 1460:20 effects [28] - 1267:4, 1268:7, 1268:20, 1270:7, 1290:13, 1291:17, 1295:13, 1295:14, 1303:4, 1305:17, 1321:1, 1321:6, 1321:21, 1322:3, 1322:15, 1323:9, 1323:16, 1323:19, 1339:16, 1360:9, 1367:13, 1388:12, 1391:13, 1396:6, 1396:20, 1449:1, 1450:22, 1452:20 effort [4] - 1261:21, 1343:4, 1344:12, 1365:7 eg [1] - 1340:24 egg [1] - 1283:9 Egli [1] - 1279:23 eight [1] - 1460:14 either [9] - 1262:9, 1262:11, 1314:7, 1341:15, 1362:22, 1363:4, 1363:17, 1432:20, 1455:7 electrochemical [2] - 1273:22, 1361:8 electrodes [1] - 1467:4 electrostatic [1] - 1382:7 elements [1] - 1363:9 elevated [2] - 1320:7, 1320:9 elevation [1] - 1401:4 eliminate [1] - 1292:2 eliminated [1] - 1285:12 eliminating [3] - 1285:15, 1407:20, 1409:22 elimination [6] -
E			
earliest [1] - 1279:23 early [3] - 1289:3, 1298:17, 1300:22 ease [1] - 1275:4 easily [1] - 1302:13 EAST [1] - 1256:7 easy [1] - 1311:22 Eberl [1] - 1298:5 Education [1] - 1259:1 Effect [1] - 1452:15 effect [41] - 1291:2, 1292:22, 1293:2, 1297:10, 1297:15, 1301:25, 1305:11, 1305:12, 1308:8, 1308:17, 1312:8, 1315:14, 1316:7,			

1285:14, 1404:1, 1404:10, 1404:17, 1404:22, 1405:2 ELMO [1] - 1300:10 elsewhere [1] - 1308:11 emits [1] - 1283:8 emitted [1] - 1322:6 employing [1] - 1310:18 encountered [1] - 1291:25 end [5] - 1396:23, 1407:17, 1418:4, 1425:10, 1444:19 ended [1] - 1396:23 endometriosis [1] - 1454:23 ends [1] - 1297:11 engaged [1] - 1258:24 English [1] - 1393:2 engulf [1] - 1292:5 engulfed [1] - 1292:12 enhances [1] - 1455:6 enter [2] - 1282:23, 1305:3 enters [1] - 1370:5 entire [2] - 1352:3, 1395:24 entirely [2] - 1333:3, 1338:12 ENTITLED [1] - 1470:6 entitled [2] - 1383:11, 1452:14 entrapped [1] - 1389:3 envelope [2] - 1326:22, 1327:24 environment [1] - 1339:24 environmental [6] - 1322:8, 1339:10, 1354:19, 1355:5, 1355:25, 1455:6 enzyme [1] - 1289:19 epidemiologic [17] - 1261:15, 1274:20, 1278:5, 1311:4, 1331:4, 1333:10, 1334:8, 1334:16, 1334:19, 1334:21, 1349:6, 1393:1, 1394:15, 1406:2, 1445:23, 1453:17, 1456:13 epidemiological [13] - 1259:17, 1274:16	1278:9, 1311:13, 1328:18, 1348:22, 1354:13, 1394:18, 1410:5, 1412:20, 1427:24, 1435:20, 1447:24 epidemiologist [1] - 1276:17 epidemiologists [4] - 1406:15, 1406:18, 1407:5, 1407:8 Epidemiology [1] - 1411:5 epidemiology [11] - 1276:16, 1278:18, 1312:17, 1312:18, 1407:11, 1409:16, 1411:3, 1411:9, 1411:16, 1437:14, 1458:14 epigenetic [1] - 1295:14 epithelial [12] - 1260:11, 1277:5, 1303:11, 1304:1, 1308:5, 1308:22, 1376:8, 1376:9, 1408:6, 1412:11, 1439:24, 1455:6 epithelium [8] - 1301:4, 1386:5, 1386:7, 1386:25, 1388:11, 1388:23, 1388:24, 1389:19 equipment [1] - 1450:13 equivalent [1] - 1439:25 error [1] - 1433:24 errors [2] - 1325:17, 1326:11 escalator [1] - 1285:9 Eslick [1] - 1275:22 ESQUIRE [10] - 1256:12, 1256:12, 1256:14, 1256:16, 1256:17, 1256:18, 1256:20, 1256:20, 1256:22, 1257:6 ESQUIRES [7] - 1256:11, 1256:13, 1256:16, 1256:18, 1256:19, 1256:21, 1257:5 essentially [11] - 1274:21, 1279:4, 1288:2, 1302:20,	1306:3, 1311:23, 1375:20, 1395:24, 1397:15, 1453:3, 1456:24 established [3] - 1269:20, 1325:15, 1355:9 establishes [1] - 1393:19 estimate [11] - 1325:9, 1325:23, 1326:2, 1326:6, 1326:11, 1328:3, 1369:7, 1408:2, 1408:21, 1430:1, 1458:8 estimated [1] - 1350:7 estimates [1] - 1328:1 estimating [2] - 1323:3, 1325:16 estimation [5] - 1324:11, 1325:4, 1422:4, 1465:12, 1466:3 et [2] - 1382:4, 1429:10 European [2] - 1425:21, 1426:10 evaluate [6] - 1262:15, 1274:15, 1287:22, 1317:17, 1447:23, 1458:2 evaluated [7] - 1262:1, 1265:22, 1273:10, 1273:12, 1274:11, 1274:25, 1288:6 evaluating [2] - 1268:5, 1278:5 evaluation [10] - 1275:7, 1277:18, 1279:15, 1281:8, 1357:4, 1358:16, 1433:12, 1434:4, 1447:1, 1447:2 evaluations [1] - 1277:24 eventually [1] - 1286:12 everyday [1] - 1268:10 evidence [58] - 1261:21, 1262:1, 1271:20, 1279:15, 1282:9, 1290:10, 1297:25, 1298:6, 1301:24, 1303:6, 1310:8, 1311:2, 1311:10, 1316:6, 1357:12, 1358:2, 1358:22, 1359:3, 1359:6, 1364:18, 1364:25, 1370:4, 1373:11, 1386:9,	1386:23, 1387:1, 1387:6, 1391:4, 1392:11, 1393:16, 1394:12, 1394:17, 1394:18, 1405:19, 1419:5, 1419:6, 1426:3, 1426:7, 1426:24, 1433:5, 1433:6, 1433:15, 1433:16, 1434:7, 1434:13, 1434:16, 1443:14, 1443:17, 1444:6, 1446:6, 1447:3, 1447:23, 1447:24, 1453:10, 1455:22, 1464:21, 1467:3, 1467:17 evolution [1] - 1285:4 exact [1] - 1443:9 exactly [6] - 1275:10, 1293:23, 1295:3, 1328:3, 1337:6, 1424:17 EXAMINATION [7] - 1258:14, 1317:6, 1354:8, 1415:7, 1440:17, 1459:11, 1467:13 examination [3] - 1338:17, 1444:20, 1466:8 examine [1] - 1396:10 examined [2] - 1372:2, 1415:11 example [14] - 1272:12, 1280:24, 1293:11, 1314:7, 1314:9, 1318:24, 1319:21, 1328:8, 1348:21, 1356:24, 1357:19, 1390:3, 1407:12, 1449:1 except [2] - 1262:20, 1456:19 excerpt [1] - 1389:15 excess [1] - 1435:2 excluded [6] - 1337:13, 1337:18, 1338:4, 1338:8, 1338:19, 1338:20 excuse [3] - 1291:6, 1292:16, 1461:20 excused [3] - 1435:23, 1467:21, 1467:22 exercise [1] - 1333:25
---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

exhaust [1] - 1450:23	1359:7, 1434:7	1391:3, 1396:22,	1366:19, 1366:24,
exhibit [4] - 1266:12, 1381:21, 1423:17, 1435:11	experiments [2] - 1287:10, 1314:1	1398:9, 1422:19	1366:25, 1368:14,
Exhibit [49] - 1266:14, 1321:14, 1321:23, 1325:13, 1340:18, 1357:4, 1372:12, 1372:17, 1373:8, 1374:4, 1374:17, 1374:23, 1379:24, 1381:16, 1385:17, 1386:16, 1388:7, 1390:24, 1392:7, 1392:24, 1394:24, 1395:7, 1395:20, 1403:14, 1403:22, 1412:5, 1412:8, 1412:24, 1413:10, 1413:18, 1418:5, 1419:13, 1422:15, 1427:20, 1429:7, 1431:2, 1431:10, 1431:18, 1433:9, 1434:3, 1434:5, 1434:23, 1436:24, 1444:22, 1445:20, 1448:5, 1454:11, 1461:15, 1463:2	expert [33] - 1266:21, 1266:24, 1267:16, 1267:19, 1268:1, 1268:9, 1268:21, 1271:12, 1276:9, 1292:24, 1337:13, 1339:11, 1363:13, 1363:16, 1365:17, 1365:25, 1366:6, 1377:24, 1378:3, 1378:6, 1378:7, 1411:3, 1411:4, 1411:7, 1411:8, 1411:15, 1425:12, 1432:5, 1446:18, 1448:24, 1449:9, 1449:14, 1449:21	exposes [1] - 1259:22 Exposure [1] - 1452:15 exposure [157] - 1260:5, 1261:11, 1261:12, 1274:15, 1278:20, 1282:12, 1283:1, 1283:2, 1283:18, 1286:19, 1286:21, 1288:18, 1288:23, 1288:25, 1300:15, 1306:3, 1306:10, 1309:16, 1311:7, 1311:8, 1311:23, 1312:7, 1312:10, 1313:7, 1318:4, 1319:12, 1319:15, 1320:25, 1321:4, 1322:8, 1322:13, 1322:14, 1323:3, 1323:21, 1324:10, 1324:11, 1324:15, 1324:20, 1324:22, 1325:5, 1325:10, 1325:22, 1325:24, 1326:7, 1329:13, 1329:18, 1330:6, 1331:8, 1331:11, 1331:15, 1331:25, 1332:14, 1333:22, 1335:13, 1335:18, 1336:4, 1336:6, 1336:9, 1336:12, 1336:14, 1336:23, 1337:3, 1338:5, 1338:9, 1338:10, 1338:21, 1339:21, 1341:23, 1341:25, 1349:7, 1349:8, 1349:15, 1349:17, 1349:20, 1349:25, 1350:11, 1350:12, 1350:22, 1350:23, 1351:2, 1351:6, 1351:8, 1351:16, 1351:23, 1351:25, 1352:19, 1352:25, 1354:17, 1354:19, 1354:20, 1355:8, 1355:11, 1355:17, 1355:25, 1360:5, 1360:12, 1366:10, 1366:13,	1366:25, 1368:14, 1369:11, 1369:22, 1373:5, 1375:25, 1379:15, 1388:12, 1388:18, 1389:1, 1389:9, 1394:1, 1394:18, 1395:21, 1395:22, 1395:25, 1396:4, 1397:16, 1398:8, 1398:12, 1398:20, 1399:10, 1401:19, 1402:5, 1402:8, 1402:9, 1402:15, 1404:13, 1404:14, 1414:6, 1435:21, 1437:15, 1437:17, 1439:14, 1439:16, 1439:20, 1441:3, 1441:24, 1442:2, 1442:3, 1442:7, 1442:10, 1444:4, 1444:5, 1454:16, 1455:6, 1458:6, 1458:12, 1463:20, 1465:11, 1465:12, 1465:18, 1466:3
Exhibits [1] - 1321:11	expertise [10] - 1267:21, 1268:21, 1271:16, 1322:7, 1344:6, 1344:17, 1345:2, 1345:4, 1376:17, 1378:4	experts [7] - 1321:19, 1342:23, 1343:8, 1343:12, 1365:11, 1366:1, 1366:2	exposure-related [1] - 1396:4
exhibits [2] - 1321:13, 1374:7	explain [6] - 1313:20, 1317:13, 1322:16, 1338:13, 1449:24, 1453:6	explain [6] - 1313:20, 1317:13, 1322:16, 1338:13, 1449:24, 1453:6	exposures [6] - 1325:21, 1339:10, 1351:1, 1351:14, 1351:15, 1451:21
exist [6] - 1262:18, 1262:19, 1286:1, 1286:14, 1424:14, 1426:10	explained [1] - 1296:8	explaining [1] - 1437:24	expressed [8] - 1347:11, 1348:5, 1374:3, 1400:7, 1400:10, 1418:25, 1421:12, 1449:25
existence [1] - 1458:24	explanation [6] - 1267:17, 1337:21, 1388:13, 1389:11, 1422:25, 1424:23	explanations [4] - 1344:13, 1388:17, 1393:21, 1435:22	expressing [2] - 1361:16, 1362:1
exists [3] - 1272:17, 1282:3, 1309:16	exploring [1] - 1346:6	exploring [1] - 1346:6	extended [2] - 1318:1, 1352:5
expect [3] - 1281:1, 1364:23, 1456:2	exposed [25] - 1268:5, 1288:21, 1304:20, 1310:13, 1310:14, 1313:15, 1318:15, 1318:22, 1322:17, 1324:17, 1328:12, 1335:21, 1337:25, 1341:9, 1350:5, 1350:11, 1350:22, 1352:14, 1352:17, 1352:25, 1389:6,	extensive [2] - 1398:7, 1447:19	
expected [2] - 1280:15, 1441:16		extensively [1] - 1451:2	
experience [6] - 1268:1, 1270:15, 1307:14, 1406:15, 1407:4, 1407:8		extent [8] - 1271:13, 1273:20, 1286:2, 1307:20, 1319:16, 1338:7, 1363:25, 1393:22	
experienced [1] - 1437:17		external [2] - 1399:17, 1400:13	
experiment [5] - 1288:23, 1313:18, 1347:12, 1348:1, 1348:7		externally [2] - 1378:13, 1399:7	
experimental [4] - 1312:10, 1358:22,			

extrapolate [1] - 1333:18	1401:19, 1402:5,	1263:23, 1264:2,	1381:23, 1382:15,
extrapolation [2] -	1427:16, 1441:25	1264:4, 1264:14,	1382:18, 1385:17,
1398:13, 1453:10	faster [1] - 1280:14	1264:25, 1265:4,	1388:8, 1392:7, 1392:8,
extreme [1] - 1262:20	favor [2] - 1419:6,	1265:21, 1266:9,	1407:4, 1416:11,
extremely [1] - 1283:3	1420:13	1266:12, 1266:18,	1431:22, 1440:19,
F			
F-344/in [1] - 1452:16	FDA [2] - 1303:3,	1266:21, 1266:25,	FISHER [1] - 1256:7
face [1] - 1332:25	1427:11	1267:2, 1267:8,	fit [2] - 1313:5, 1405:22
fact [24] - 1261:8,	fears [1] - 1321:20	1267:11, 1267:14,	five [4] - 1288:16,
1280:16, 1281:13,	federal [2] - 1337:14,	1267:16, 1267:21,	1290:9, 1315:3, 1355:10
1293:4, 1299:17,	1427:2	1268:2, 1268:6, 1268:7,	Fletcher [1] - 1289:22
1302:17, 1322:25,	Federal [1] - 1465:10	1268:9, 1269:4, 1269:7,	FLOM [1] - 1256:18
1324:2, 1340:3, 1370:3,	feedback [1] - 1277:23	1269:11, 1269:22,	flow [1] - 1305:7
1397:24, 1407:12,	felt [8] - 1311:9, 1313:8,	1270:11, 1270:14,	fluid [2] - 1302:24,
1408:15, 1438:12,	1314:11, 1333:24,	1270:15, 1270:17,	1389:3
1439:18, 1442:6,	1393:16, 1417:15,	1271:21, 1272:13,	fluids [1] - 1305:7
1444:11, 1446:9,	1423:20, 1436:8	1273:1, 1273:4, 1293:6,	fly [1] - 1332:25
1449:11, 1449:13,	female [11] - 1259:21,	1293:10, 1293:11,	focus [7] - 1270:11,
1457:15, 1460:24,	1279:3, 1279:21,	1293:17, 1306:13,	1272:2, 1278:20,
1461:5, 1467:2	1279:25, 1281:14,	1444:13, 1455:16,	1282:17, 1323:12,
factor [2] - 1409:15,	1376:4, 1391:13,	1455:23, 1457:22,	1399:3, 1411:19
1411:20	1396:11, 1396:15,	1458:25	follicular [1] - 1389:3
factors [9] - 1304:11,	1403:16, 1403:18	fight [1] - 1384:25	follow [6] - 1295:8,
1314:18, 1375:15,	few [5] - 1303:13,	figure [4] - 1295:10,	1359:14, 1370:10,
1393:2, 1393:3,	1303:14, 1320:6,	1304:10, 1333:6, 1335:1	1375:1, 1397:2, 1458:1
1405:11, 1405:15,	1376:16, 1459:7	files [1] - 1262:12	follow-up [2] - 1397:2,
1424:6, 1435:9	fiber [9] - 1270:25,	fill [2] - 1332:9, 1345:16	1458:1
facts [1] - 1466:13	1272:8, 1272:9,	filtered [1] - 1274:24	followed [1] - 1261:10
faculty [1] - 1411:4	1272:19, 1291:19,	final [4] - 1357:3, 1436:9,	FOLLOWING [1] -
failed [4] - 1337:19,	1291:20, 1292:5,	1461:16, 1462:2	1470:4
1354:23, 1440:21,	1292:11, 1341:12	finally [3] - 1273:4,	following [1] - 1389:14
1467:2	fiber' [1] - 1272:18	1289:21, 1427:18	follows [1] - 1258:12
fails [1] - 1345:14	fibers [38] - 1260:4,	findings [15] - 1288:10,	Food [1] - 1282:2
failure [2] - 1337:9,	1263:21, 1267:5,	1288:19, 1291:10,	food [1] - 1363:25
1466:10	1270:7, 1270:8,	1291:14, 1298:23,	FOR [1] - 1256:1
fair [10] - 1269:10,	1272:12, 1272:16,	1341:4, 1346:15,	force [1] - 1443:12
1273:4, 1307:8,	1272:17, 1272:23,	1346:19, 1349:13,	foreign [11] - 1285:5,
1335:19, 1445:2,	1273:2, 1290:25,	1356:8, 1387:23,	1373:12, 1381:12,
1445:5, 1447:14,	1291:1, 1291:3, 1291:4,	1390:25, 1391:2,	1382:5, 1382:10,
1447:20, 1457:18,	1291:11, 1291:15,	1423:6, 1447:11	1391:4, 1391:15,
1458:17	1291:16, 1291:24,	fine [2] - 1454:8, 1456:9	1391:19, 1448:14,
fairly [3] - 1308:14,	1292:13, 1292:21,	finish [2] - 1297:7,	1448:16, 1449:2
1337:21, 1458:18	1293:2, 1293:16,	1315:4	forest [5] - 1275:4,
fall [1] - 1308:15	1293:20, 1295:5,	fire [1] - 1320:7	1275:5, 1275:6,
fallopian [7] - 1278:25,	1340:5, 1340:11,	first [32] - 1258:11,	1278:12, 1311:12
1279:17, 1280:13,	1341:1, 1341:5,	1259:15, 1262:4,	forgotten [1] - 1456:11
1379:12, 1379:15,	1341:13, 1342:11,	1262:5, 1311:3,	form [14] - 1262:25,
1399:8, 1444:12	1343:16, 1358:4,	1321:11, 1321:18,	1263:1, 1263:3,
familiar [5] - 1263:12,	1358:9, 1358:24,	1323:7, 1324:5,	1276:14, 1277:6,
1389:21, 1421:4,	1359:4, 1370:21, 1434:9	1324:19, 1324:21,	1289:3, 1306:13,
1425:16, 1432:1	fibrosis [1] - 1373:12	1324:25, 1325:14,	1320:2, 1348:13,
far [6] - 1273:7, 1328:23,	fibrotic [1] - 1380:8	1334:7, 1340:19,	1360:21, 1361:8,
	fibrous [48] - 1260:4,	1347:8, 1372:13,	1391:14, 1450:18,
	1263:3, 1263:21,	1373:3, 1376:2,	

1450:24 formations [1] - 1267:19 formed [6] - 1261:23, 1346:23, 1378:11, 1389:24, 1402:19, 1403:2 former [1] - 1270:4 forming [7] - 1329:17, 1330:4, 1336:11, 1336:21, 1349:5, 1375:12, 1417:15 forms [4] - 1357:13, 1360:24, 1361:2, 1378:1 formulating [3] - 1326:1, 1326:5, 1405:12 formulation [1] - 1368:10 forth [6] - 1275:2, 1290:16, 1312:15, 1350:8, 1354:21, 1426:9 fortunately [1] - 1322:9 forward [1] - 1277:20 foundation [3] - 1276:19, 1346:5, 1445:14 four [4] - 1383:18, 1386:3, 1389:11, 1424:2 fourth [1] - 1430:2 fragmentation [1] - 1289:17 fragrance [16] - 1263:10, 1274:2, 1274:9, 1306:24, 1362:23, 1362:25, 1363:4, 1367:11, 1367:15, 1367:22, 1367:25, 1368:7, 1368:14, 1368:22, 1369:5, 1457:21 fragrances [2] - 1274:6, 1369:7 frank [2] - 1387:1, 1387:4 frankly [1] - 1296:23 FREDA [1] - 1256:9 frequency [8] - 1328:14, 1328:20, 1333:12, 1368:13, 1368:17, 1368:19, 1457:24, 1458:11 frequent [1] - 1458:9 frequently [1] - 1280:10 front [8] - 1321:10, 1341:18, 1372:11, 1381:19, 1385:18,	1403:3, 1441:20, 1447:7 frustration [1] - 1292:15 full [9] - 1258:17, 1293:13, 1325:14, 1381:23, 1383:17, 1386:17, 1386:21, 1388:8, 1443:12 function [1] - 1314:8 fundamental [2] - 1395:18, 1419:3 funding [1] - 1436:20 fur [1] - 1398:10 FURTHER [1] - 1467:13 future [1] - 1389:16	1403:6, 1412:10, 1413:2, 1413:13, 1420:19, 1422:19, 1443:20, 1447:25, 1453:21, 1459:1, 1462:8, 1467:17 genotoxic [5] - 1295:13, 1437:10, 1437:22, 1438:6, 1438:8 genotoxicity [10] - 1294:12, 1294:13, 1294:22, 1295:2, 1295:7, 1295:11, 1295:17, 1295:23, 1296:7, 1296:21 genotoxicity [1] - 1291:22 geologic [1] - 1347:16 geological [3] - 1264:6, 1267:19 geologist [1] - 1339:6 geology [3] - 1266:24, 1268:22, 1268:23 GEREL [1] - 1256:13 Gertig [10] - 1415:21, 1419:19, 1420:4, 1420:6, 1420:7, 1420:9, 1420:13, 1460:13, 1460:17, 1462:4 giant [1] - 1373:12 girls [3] - 1354:18, 1354:22, 1355:24 given [6] - 1284:22, 1292:20, 1328:25, 1335:25, 1408:10, 1417:16 glad [1] - 1289:11 glove [1] - 1280:25 gloves [2] - 1302:12, 1303:4 glue [1] - 1302:21 glutathione [2] - 1289:10, 1289:18 Gonzales [2] - 1416:25, 1419:18 GOTSHAL [1] - 1256:21 gradient [1] - 1312:12 Graham [1] - 1298:10 gram [1] - 1383:17 granulomas [5] - 1302:13, 1384:9, 1384:13, 1384:14, 1384:17 Granulomatosis [1] -	1383:12 granulomatosis [3] - 1383:13, 1384:3, 1384:5 granulomatous [1] - 1302:10 graphic [2] - 1261:8, 1275:8 great [2] - 1368:1, 1440:5 greater [10] - 1304:19, 1318:21, 1401:19, 1402:6, 1402:10, 1402:16, 1406:20, 1408:17, 1441:25, 1442:4 greatest [1] - 1304:20 Green [3] - 1429:10, 1429:25, 1447:9 grounds [1] - 1338:19 group [6] - 1355:5, 1355:7, 1397:12, 1416:1, 1422:9, 1425:5 Group [10] - 1273:3, 1273:5, 1273:14, 1273:15, 1310:2, 1319:24, 1356:23, 1360:2, 1432:9, 1435:15 Groups [1] - 1391:3 groups [4] - 1325:22, 1325:25, 1356:20, 1391:3 grown [1] - 1388:23 grows [2] - 1272:20, 1286:10 growth [5] - 1260:6, 1286:11, 1293:22, 1296:18, 1380:10 guess [3] - 1265:6, 1300:3, 1352:8 guesswork [1] - 1466:24 guidelines [1] - 1310:19 guts [1] - 1296:22 gynecologic [1] - 1376:18 gynecological [3] - 1400:8, 1400:11, 1400:12 gynecologist [4] - 1283:23, 1283:24, 1377:8, 1400:9 gynecologists [1] - 1404:19
-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

H			
habit [2] - 1272:21, 1291:19	1436:25	1363:4, 1363:8, 1363:20, 1365:1, 1365:8, 1365:13, 1365:19, 1366:7, 1366:11, 1366:20, 1367:8, 1367:10, 1394:4, 1438:11, 1438:12, 1439:18, 1441:8, 1443:13, 1458:25	1264:23, 1265:20, 1266:23, 1267:18, 1267:24, 1268:16, 1270:22, 1271:8, 1271:22, 1275:25, 1276:2, 1276:7, 1292:16, 1293:14, 1295:3, 1295:16, 1296:7, 1296:20, 1297:7, 1297:21, 1298:24, 1299:13, 1300:8, 1300:9, 1301:15, 1316:9, 1321:16, 1327:2, 1332:16, 1333:13, 1336:16, 1339:19, 1345:15, 1346:5, 1347:21, 1351:19, 1352:20, 1353:7, 1357:6, 1361:22, 1366:16, 1368:3, 1372:14, 1376:24, 1377:19, 1381:17, 1395:1, 1410:18, 1411:12, 1414:15, 1416:3, 1427:3, 1428:11, 1431:3, 1442:20, 1445:14, 1454:6, 1456:8, 1459:5, 1459:8, 1467:10
habitual [5] - 1317:13, 1317:19, 1317:25, 1318:5, 1442:9	habits [2] - 1324:23, 1325:5	Health [36] - 1258:22, 1261:7, 1282:7, 1316:1, 1316:4, 1321:24, 1411:6, 1415:16, 1415:24, 1425:7, 1426:15, 1427:14, 1429:19, 1430:15, 1430:23, 1435:14, 1435:19, 1436:7, 1436:14, 1436:21, 1438:1, 1438:2, 1444:24, 1444:25, 1445:2, 1445:3, 1445:11, 1445:18, 1447:6, 1457:2, 1457:15, 1463:3, 1463:17	help [1] - 1305:22
half [1] - 1386:4	headline [1] - 1321:18	health [18] - 1259:16, 1268:20, 1270:7, 1320:17, 1320:21, 1321:1, 1321:6, 1321:21, 1322:3, 1322:14, 1324:9, 1324:10, 1325:3, 1339:16, 1427:10, 1450:22, 1465:16, 1466:2	helpful [3] - 1292:8, 1418:19, 1458:8
Halme [1] - 1280:8	heal [1] - 1283:11	highlighted [2] - 1412:9, 1462:5	helps [1] - 1291:7
Hamilton [25] - 1298:14, 1298:19, 1298:20, 1299:5, 1299:8, 1299:13, 1299:16, 1299:17, 1300:1, 1300:5, 1300:12, 1300:23, 1301:10, 1385:13, 1385:18, 1385:22, 1387:10, 1387:14, 1387:18, 1446:24, 1447:1, 1463:9, 1463:14, 1464:8, 1464:19	healing [3] - 1283:14, 1283:21, 1302:22	heterogeneity [9] - 1422:25, 1423:4, 1423:5, 1423:9, 1456:12, 1456:16, 1456:19, 1456:24, 1461:23	heterogeneity [9] -
hand [23] - 1301:15, 1301:16, 1324:6, 1324:25, 1325:12, 1352:13, 1352:15, 1357:10, 1372:20, 1373:3, 1381:22, 1382:18, 1386:17, 1386:21, 1388:8, 1391:1, 1391:20, 1393:24, 1397:8, 1401:1, 1413:19, 1422:15, 1423:7	headline [1] - 1321:18	high [6] - 1306:10, 1306:16, 1306:20, 1389:1, 1389:7, 1389:9	high [6] -
handy [2] - 1395:3, 1395:4	heal [1] - 1283:11	higher [9] - 1318:17, 1319:5, 1340:8, 1341:14, 1364:19, 1365:1, 1401:2, 1401:5, 1401:9	higher [9] -
hard [3] - 1347:19, 1378:3, 1426:7	healing [3] - 1283:14, 1283:21, 1302:22	highlighted [2] - 1412:9, 1462:5	highlighted [2] -
hard-pressed [1] - 1347:19	health [18] - 1259:16, 1268:20, 1270:7, 1320:17, 1320:21, 1321:1, 1321:6, 1321:21, 1322:3, 1322:14, 1324:9, 1324:10, 1325:3, 1339:16, 1427:10, 1450:22, 1465:16, 1466:2	highly [1] - 1314:22	highly [1] -
hardness [1] - 1382:6	hear [4] - 1266:4, 1276:15, 1278:19, 1279:13	Hill [12] - 1310:4, 1310:16, 1310:19, 1310:22, 1310:25, 1313:17, 1405:6, 1405:11, 1409:5, 1409:13, 1409:15, 1411:18	Hill [12] -
Harlow [2] - 1430:7, 1447:9	heard [4] - 1275:20, 1282:8, 1293:9, 1421:15	hired [2] - 1342:23, 1343:12	hired [2] -
harm [3] - 1331:22, 1332:5, 1426:3	heavy [34] - 1273:8, 1306:20, 1308:2, 1349:14, 1349:20, 1350:22, 1351:7, 1351:25, 1354:17, 1355:11, 1355:16, 1359:16, 1359:22, 1362:16, 1362:22	histologic [1] - 1462:10	histologic [1] -
harmful [10] - 1318:17, 1323:16, 1323:19, 1329:18, 1330:5, 1336:4, 1336:12, 1336:22, 1338:9, 1338:21	HEARING [1] - 1256:4	historical [1] - 1303:6	historical [1] -
harmless [2] - 1298:13, 1318:14	heavy [34] - 1273:8, 1306:20, 1308:2, 1349:14, 1349:20, 1350:22, 1351:7, 1351:25, 1354:17, 1355:11, 1355:16, 1359:16, 1359:22, 1362:16, 1362:22	historically [1] - 1263:17	historically [1] -
has-yet-to-be [1] -		hold [2] - 1268:8, 1339:10	hold [2] -

humans [22] - 1291:5, 1301:24, 1302:3, 1302:11, 1303:7, 1312:16, 1319:25, 1323:13, 1357:12, 1358:2, 1378:12, 1387:22, 1398:15, 1398:19, 1432:13, 1433:4, 1433:5, 1433:16, 1435:16, 1444:7, 1453:9, 1453:11 hygiene [2] - 1317:14, 1328:4 hygienic [4] - 1282:21, 1312:3, 1401:25, 1409:23 hyperoxia [1] - 1319:5 hypothesis [8] - 1392:19, 1392:21, 1393:4, 1393:8, 1393:17, 1393:19, 1419:6, 1425:3 hypothetically [1] - 1456:3	IARC's [5] - 1356:9, 1356:12, 1359:8, 1431:22, 1434:19 idea [4] - 1326:23, 1364:3, 1364:12, 1404:18 identification [1] - 1261:9 identified [5] - 1359:23, 1375:1, 1413:21, 1417:24, 1462:7 identify [3] - 1290:21, 1360:1, 1441:8 II [2] - 1396:5, 1405:1 III [3] - 1391:4, 1403:23, 1435:15 illustrate [2] - 1268:18, 1302:8 illustration [2] - 1291:6, 1305:22 illustrations [1] - 1302:7 Imerys [2] - 1345:22, 1366:3 Imerys' [2] - 1344:15, 1344:25 immaterial [2] - 1362:14, 1365:4 immune [9] - 1291:25, 1292:1, 1292:4, 1380:9, 1384:6, 1384:21, 1384:25, 1387:18, 1437:8 immunologic [1] - 1290:14 Immunosuppression [1] - 1383:11 immunosuppression [2] - 1384:24, 1385:3 impact [4] - 1293:9, 1394:22, 1435:3, 1460:12 implanted [1] - 1380:6 import [1] - 1461:3 importance [1] - 1291:1 important [21] - 1287:5, 1287:8, 1288:12, 1288:19, 1289:9, 1289:18, 1290:3, 1304:7, 1307:4, 1319:9, 1324:8, 1324:9, 1325:3, 1337:10, 1375:12, 1388:16, 1417:15,	1419:25, 1420:1, 1436:8, 1466:1 improper [2] - 1430:23, 1450:14 impurities [2] - 1363:9, 1367:4 IN [2] - 1256:4, 1470:5 inactivation [1] - 1296:15 inadequate [3] - 1358:22, 1359:6, 1359:8 incidence [3] - 1313:24, 1356:2, 1397:21 include [6] - 1263:8, 1292:23, 1293:17, 1440:21, 1461:10, 1462:3 included [20] - 1264:9, 1265:8, 1272:15, 1273:2, 1294:24, 1363:9, 1367:20, 1371:1, 1393:23, 1417:17, 1418:4, 1419:1, 1419:2, 1422:18, 1432:4, 1460:17, 1461:12, 1461:19, 1461:20, 1462:17 includes [5] - 1278:3, 1298:3, 1426:8, 1462:23 including [21] - 1260:4, 1260:6, 1263:24, 1272:20, 1273:25, 1279:6, 1281:4, 1282:24, 1290:15, 1296:13, 1340:1, 1342:20, 1345:21, 1360:23, 1378:14, 1380:9, 1403:16, 1437:8, 1439:24, 1453:23, 1461:22 inclusive [1] - 1427:15 incomplete [1] - 1346:1 inconsistency [1] - 1394:3 inconsistent [1] - 1394:12 incontrovertible [1] - 1298:6 incorporated [3] - 1263:8, 1283:14, 1364:7 incorrectly [1] - 1423:3 increase [9] - 1259:20,	1275:18, 1290:3, 1290:4, 1331:5, 1331:25, 1391:5, 1422:10, 1441:3 increased [16] - 1277:7, 1277:9, 1289:3, 1289:8, 1290:6, 1406:10, 1406:24, 1408:7, 1408:19, 1409:19, 1410:4, 1412:11, 1413:14, 1415:22, 1425:1, 1454:2 increases [9] - 1307:20, 1307:23, 1319:16, 1330:10, 1331:20, 1336:9, 1356:2, 1360:6, 1360:13 increasing [1] - 1306:4 increment [1] - 1307:24 independent [1] - 1269:21 indicate [5] - 1300:5, 1300:15, 1371:5, 1400:19, 1435:20 indicated [2] - 1271:15, 1438:8 indicates [4] - 1437:10, 1438:5, 1456:20, 1465:1 indications [1] - 1302:3 indicative [2] - 1316:7, 1457:6 indicators [1] - 1290:2 indirect [2] - 1295:11, 1297:10 indisputable [1] - 1282:7 individual [9] - 1287:11, 1306:6, 1307:5, 1325:24, 1451:21, 1456:22, 1458:3, 1458:4, 1458:20 individually [1] - 1278:10 indoor [2] - 1340:10, 1340:24 induced [2] - 1289:23, 1381:13 Induced [1] - 1383:11 industrial [3] - 1322:8, 1324:10, 1466:2 inert [1] - 1450:5 infection [2] - 1391:5, 1391:15 infections [1] - 1385:1 inferentially [1] -

1419:10	1331:15, 1333:7, 1333:9, 1333:11, 1334:1, 1334:4, 1334:6, 1334:16, 1334:18, 1334:21, 1334:25, 1345:21, 1346:11, 1350:9, 1350:20, 1351:1, 1351:3, 1361:21, 1363:2, 1364:22, 1365:22, 1367:17, 1367:24, 1368:2, 1368:20, 1368:23, 1369:3, 1369:6, 1378:19, 1409:20, 1418:15, 1450:22	injections [1] - 1384:2 injury [1] - 1292:15 inmate [1] - 1450:1 inquiry [2] - 1295:20, 1332:3 insertion [1] - 1284:5 inside [6] - 1285:16, 1361:19, 1399:12, 1399:23, 1400:19, 1464:13 insights [1] - 1437:7 insignificant [1] - 1283:1 installation [1] - 1399:10 instances [1] - 1448:20 instead [1] - 1432:12 instilled [1] - 1399:6 Institute [2] - 1261:6, 1427:11 insufficient [3] - 1370:4, 1433:4, 1433:15 intensified [1] - 1305:12 intensifies [3] - 1260:5, 1305:14, 1339:1 intensify [4] - 1267:5, 1292:22, 1293:2, 1293:21 intent [1] - 1261:22 interest [1] - 1301:3 interleukins [2] - 1290:3, 1290:16 intermittent [1] - 1389:1 internal [7] - 1264:11, 1272:7, 1343:1, 1345:22, 1366:3, 1399:18, 1455:19 internet [2] - 1262:13, 1302:7 interpose [1] - 1264:17 interpret [2] - 1318:18, 1464:23 interpretation [1] - 1461:25 interpreting [4] - 1387:23, 1398:19, 1410:16, 1423:2 interval [7] - 1429:5, 1429:14, 1429:16, 1430:2, 1430:10, 1430:13, 1430:21 intervening [1] - 1460:21 interventions [2] - 1313:19, 1313:22 intrabursal [1] - 1300:16
inflammation [69] - 1260:1, 1283:16, 1285:23, 1288:1, 1290:11, 1290:15, 1290:23, 1292:21, 1294:23, 1295:10, 1295:12, 1296:13, 1296:18, 1297:11, 1297:20, 1298:1, 1301:22, 1302:4, 1302:10, 1302:15, 1302:22, 1303:7, 1303:8, 1303:9, 1303:10, 1304:1, 1304:12, 1304:16, 1304:19, 1305:1, 1305:5, 1305:8, 1309:21, 1309:24, 1311:6, 1313:3, 1315:11, 1373:17, 1376:8, 1378:9, 1378:14, 1378:18, 1379:19, 1380:8, 1380:14, 1384:15, 1387:10, 1387:15, 1390:4, 1390:6, 1390:11, 1390:15, 1390:18, 1390:20, 1390:22, 1392:16, 1393:5, 1393:11, 1397:18, 1397:25, 1402:21, 1403:5, 1446:2, 1446:7, 1447:4, 1449:3, 1452:11, 1455:7		
inflammatory [16] - 1260:6, 1288:4, 1293:21, 1296:14, 1297:15, 1301:25, 1303:1, 1303:17, 1305:10, 1305:12, 1309:22, 1380:9, 1384:6, 1391:5, 1397:19, 1437:9	initiate [1] - 1296:12 initiates [1] - 1455:7 initiation [7] - 1286:6, 1286:14, 1286:16, 1287:3, 1297:12, 1315:10, 1451:12 jected [12] - 1298:15, 1301:5, 1383:17, 1385:24, 1386:3, 1386:25, 1388:11, 1388:25, 1389:6, 1451:3, 1464:9, 1464:20	
influence [2] - 1304:11, 1398:24	injecting [2] - 1302:20, 1400:15 injection [4] - 1300:16, 1383:18, 1399:22, 1400:18	
influenced [1] - 1450:10 influences [1] - 1424:5 information [40] - 1264:4, 1275:10, 1307:21, 1312:5, 1318:7, 1322:17, 1327:15, 1330:14,		

<p>itself [9] - 1283:11, 1285:4, 1295:12, 1298:22, 1299:6, 1370:9, 1370:15, 1464:10, 1464:11 Iturralde [1] - 1280:2 IV [1] - 1391:4</p>	<p style="text-align: center;">K</p> <p>keeping [1] - 1333:3 Keskin [6] - 1389:21, 1390:3, 1446:24, 1447:2, 1463:11, 1463:14 Kettering [1] - 1259:7 kill [1] - 1318:24 killed [1] - 1451:14 kind [7] - 1261:2, 1278:16, 1291:16, 1314:6, 1353:3, 1386:4, 1436:5 kinds [1] - 1279:19 knowingly [1] - 1377:5 knowledge [7] - 1268:2, 1269:21, 1320:5, 1332:7, 1332:10, 1378:25, 1445:15 known [13] - 1261:12, 1273:5, 1292:13, 1302:9, 1305:14, 1319:11, 1319:21, 1331:23, 1331:24, 1360:24, 1375:17, 1408:3, 1432:16 knows [1] - 1292:25 Krekeler [1] - 1268:22 Krewski [9] - 1431:7, 1431:14, 1431:16, 1435:13, 1435:18, 1436:1, 1445:8, 1445:11 Krewski's [1] - 1436:25 Kunz [1] - 1280:11</p>	<p>large [3] - 1285:8, 1347:4, 1450:24 larger [3] - 1318:20, 1322:6, 1422:10 larynx [2] - 1357:16, 1357:22 last [21] - 1263:13, 1275:19, 1275:21, 1315:20, 1386:17, 1386:21, 1397:9, 1398:4, 1398:5, 1403:23, 1407:25, 1421:15, 1425:9, 1425:11, 1431:11, 1438:9, 1457:20, 1461:18, 1462:22, 1463:8, 1466:22 lasted [2] - 1395:22, 1395:25 latency [3] - 1286:17, 1286:18, 1286:21 latter [1] - 1437:6 law [1] - 1332:25 laws [1] - 1313:12 lawyer [1] - 1296:24 lawyer-supplied [1] - 1296:24 lays [1] - 1392:15 lead [4] - 1309:15, 1367:18, 1387:11, 1390:6 leading [4] - 1273:23, 1293:11, 1390:18, 1397:25 leads [2] - 1319:5, 1390:11 least [10] - 1304:7, 1307:1, 1310:1, 1345:19, 1361:15, 1361:25, 1401:10, 1438:4, 1440:22, 1453:6 leave [1] - 1365:11 leaves [1] - 1283:9 led [2] - 1387:15, 1387:19 LEE [1] - 1256:20 left [14] - 1269:8, 1272:6, 1291:21, 1292:6, 1292:17, 1301:15, 1306:5, 1324:6, 1324:25, 1372:20, 1373:3, 1381:22, 1413:19, 1456:15</p>	<p>left-hand [7] - 1301:15, 1324:6, 1324:25, 1372:20, 1373:3, 1381:22, 1413:19 legal [5] - 1332:17, 1426:8, 1449:20, 1466:14, 1466:16 legitimate [1] - 1389:10 LEIGH [1] - 1256:12 lesions [1] - 1396:4 less [8] - 1307:3, 1311:22, 1315:3, 1341:12, 1375:22, 1386:4, 1423:20, 1423:21 lesser [1] - 1306:22 leukemia [1] - 1320:2 level [34] - 1290:23, 1307:15, 1307:21, 1312:16, 1319:12, 1320:25, 1321:6, 1322:3, 1322:14, 1324:15, 1324:20, 1324:22, 1325:4, 1329:12, 1329:18, 1330:5, 1331:15, 1332:4, 1332:14, 1333:18, 1335:1, 1336:3, 1336:6, 1336:12, 1336:22, 1337:25, 1338:5, 1338:9, 1338:21, 1352:19, 1367:25, 1465:12, 1466:3 levels [15] - 1318:17, 1320:6, 1320:15, 1320:17, 1320:21, 1321:5, 1321:20, 1322:2, 1323:3, 1324:11, 1325:10, 1341:22, 1341:24, 1364:19, 1365:1 liberated [1] - 1361:9 liberation [1] - 1296:14 life [2] - 1319:18, 1370:20 Lifetime [1] - 1452:15 lifetime [4] - 1395:24, 1396:1, 1396:2, 1398:7 ligation [1] - 1313:22 light [1] - 1451:3 likelihood [1] - 1420:14 likely [5] - 1369:10,</p>
<p>J&J [2] - 1343:20, 1366:3 J&J's [7] - 1344:7, 1365:8, 1365:14, 1365:19, 1365:23, 1366:8, 1367:16 Jenkins [1] - 1298:10 JERSEY [3] - 1256:1, 1256:16, 1256:17 Jersey [1] - 1427:4 job [3] - 1365:11, 1450:10, 1450:11 JOHN [1] - 1256:18 JOHNSON [2] - 1256:4 Johnson [22] - 1256:22, 1264:11, 1342:20, 1342:25, 1343:6, 1343:13, 1343:14, 1343:16, 1343:17, 1344:14, 1344:19, 1344:24, 1345:22, 1352:16, 1353:1 Johnson's [16] - 1259:15, 1260:3, 1260:8, 1260:10, 1262:15, 1262:22, 1262:24, 1263:21, 1264:24, 1273:9, 1274:11, 1342:20, 1342:25, 1344:19, 1352:16, 1443:5 Judge [3] - 1278:19, 1466:23, 1467:1 JULIE [1] - 1256:17 July [1] - 1431:5 JULY [1] - 1256:4 jump [1] - 1369:8 jumping [1] - 1325:12 June [1] - 1259:4 jurisdiction [2] - 1332:13, 1332:19 Justice [1] - 1337:16</p>	<p style="text-align: center;">L</p> <p>labeled [2] - 1280:3, 1321:13 Laboratory [1] - 1259:7 laboratory [3] - 1287:10, 1287:14, 1380:7 laboratory-designed [1] - 1287:10 lack [4] - 1346:5, 1394:2, 1404:9, 1424:23 Lack [1] - 1452:15 lacks [1] - 1445:14 lactate [1] - 1289:6 language [4] - 1296:25, 1393:2, 1404:21, 1433:25 languages [1] - 1274:23</p>	<p>labeled [2] - 1280:3, 1321:13 Laboratory [1] - 1259:7 laboratory [3] - 1287:10, 1287:14, 1380:7 laboratory-designed [1] - 1287:10 lack [4] - 1346:5, 1394:2, 1404:9, 1424:23 Lack [1] - 1452:15 lacks [1] - 1445:14 lactate [1] - 1289:6 language [4] - 1296:25, 1393:2, 1404:21, 1433:25 languages [1] - 1274:23</p>	<p>labeled [2] - 1280:3, 1321:13 Laboratory [1] - 1259:7 laboratory [3] - 1287:10, 1287:14, 1380:7 laboratory-designed [1] - 1287:10 lack [4] - 1346:5, 1394:2, 1404:9, 1424:23 Lack [1] - 1452:15 lacks [1] - 1445:14 lactate [1] - 1289:6 language [4] - 1296:25, 1393:2, 1404:21, 1433:25 languages [1] - 1274:23</p>

1375:22, 1422:8, 1426:20, 1452:10 limitations [1] - 1398:14 limited [4] - 1359:3, 1394:2, 1434:7, 1462:10 limits [1] - 1323:22 line [31] - 1289:15, 1295:19, 1330:1, 1333:16, 1336:19, 1344:22, 1344:23, 1345:7, 1345:8, 1351:21, 1361:24, 1377:1, 1378:3, 1380:5, 1381:4, 1381:5, 1418:23, 1440:25, 1441:1, 1441:22, 1442:5, 1448:10, 1448:11, 1449:22, 1463:8 lines [17] - 1288:14, 1288:21, 1289:23, 1327:4, 1350:19, 1352:22, 1364:11, 1366:18, 1368:5, 1369:2, 1377:21, 1378:23, 1402:2, 1402:13, 1402:14, 1410:20, 1416:5 link [2] - 1308:21, 1394:1 linked [1] - 1308:4 linking [3] - 1309:12, 1394:18, 1467:3 links [1] - 1375:24 lipid [1] - 1289:17 list [13] - 1265:1, 1265:2, 1274:4, 1274:25, 1359:23, 1365:24, 1374:21, 1382:23, 1395:13, 1417:17, 1418:6, 1419:22, 1432:5 listed [6] - 1281:22, 1374:17, 1418:3, 1418:10, 1431:12, 1462:21 lists [4] - 1382:15, 1395:21, 1419:15, 1427:23 liter [1] - 1341:13 literature [31] - 1261:15, 1261:17, 1262:8, 1262:14, 1263:14, 1264:1, 1264:3, 1270:25, 1274:14,	1274:20, 1274:22, 1275:7, 1277:15, 1278:5, 1279:7, 1279:11, 1284:2, 1303:21, 1307:13, 1316:5, 1328:16, 1328:18, 1374:17, 1374:22, 1393:2, 1445:23, 1450:20, 1450:24, 1455:22, 1456:13, 1463:21 litigation [13] - 1261:3, 1262:10, 1264:9, 1317:12, 1346:3, 1346:17, 1361:15, 1362:1, 1365:18, 1366:7, 1373:21, 1375:16, 1395:17 live [1] - 1319:3 lives [7] - 1333:23, 1341:25, 1407:17, 1407:21, 1408:13, 1408:21, 1409:10 living [1] - 1323:10 load [1] - 1382:7 local [2] - 1298:6, 1300:18 locate [1] - 1308:17 located [3] - 1451:11, 1463:20, 1463:24 location [1] - 1380:22 locations [4] - 1262:11, 1340:4, 1340:7, 1347:15 LOCKE [1] - 1257:6 Lockey [10] - 1270:1, 1270:4, 1270:23, 1271:4, 1271:7, 1271:9, 1271:24, 1272:1, 1272:5, 1272:6 long-term [4] - 1296:17, 1388:25, 1389:6, 1389:9 Longo [20] - 1264:10, 1265:13, 1266:2, 1266:5, 1266:7, 1266:19, 1267:9, 1269:1, 1269:10, 1270:19, 1270:20, 1271:2, 1271:3, 1271:10, 1271:12, 1271:14, 1271:17, 1345:13, 1345:24, 1365:13 Longo's [12] - 1265:5,	1267:1, 1269:17, 1269:19, 1271:18, 1345:23, 1346:2, 1346:10, 1346:15, 1346:17, 1455:15, 1456:1 look [59] - 1260:25, 1263:18, 1266:15, 1281:16, 1286:3, 1287:9, 1287:11, 1296:9, 1318:6, 1321:9, 1323:24, 1324:5, 1326:25, 1340:17, 1340:18, 1341:17, 1355:21, 1357:3, 1366:19, 1379:22, 1381:7, 1381:14, 1383:2, 1383:10, 1385:16, 1386:17, 1388:7, 1390:24, 1392:24, 1393:24, 1394:23, 1397:3, 1406:18, 1412:5, 1412:8, 1413:18, 1420:7, 1421:22, 1421:25, 1427:12, 1427:19, 1429:24, 1431:1, 1431:10, 1431:17, 1433:9, 1434:1, 1434:4, 1434:23, 1441:10, 1442:9, 1444:23, 1448:1, 1450:8, 1455:1, 1458:5, 1465:21 looked [21] - 1274:14, 1274:16, 1277:2, 1279:24, 1281:19, 1288:3, 1289:22, 1311:11, 1312:9, 1347:14, 1349:6, 1405:11, 1415:17, 1419:1, 1420:12, 1422:6, 1424:13, 1444:7, 1450:20, 1461:8, 1461:12 looking [15] - 1262:7, 1267:9, 1278:9, 1279:19, 1311:2, 1311:13, 1315:21, 1341:19, 1380:23, 1383:24, 1409:16, 1418:6, 1435:12, 1453:14, 1462:13	looks [7] - 1265:9, 1265:18, 1269:22, 1270:18, 1271:25, 1275:9, 1275:17 lovely [1] - 1442:25 low [4] - 1306:9, 1318:20, 1318:23, 1422:24 lower [3] - 1292:7, 1301:15, 1401:12 lubricant [1] - 1302:12 lubricants [1] - 1303:3 lunch [2] - 1353:8, 1448:5 luncheon [1] - 1353:12 lung [12] - 1284:25, 1285:4, 1285:7, 1285:11, 1357:16, 1357:22, 1358:5, 1383:13, 1396:10, 1396:24, 1458:16, 1467:4 lungs [2] - 1285:2, 1302:21 lymphatic [1] - 1285:17
M			
M.D [2] - 1259:9, 1468:9 macromolecular [1] - 1361:11 macromolecules [1] - 1273:25 macrophage [3] - 1292:5, 1292:12, 1292:14 macrophages [2] - 1285:7, 1293:20 Magistrate [2] - 1466:23, 1467:1 magnitude [2] - 1454:2, 1456:21 major [1] - 1262:24 majority [3] - 1275:13, 1275:15, 1311:17 malignant [1] - 1389:18 mammalian [2] - 1433:6, 1433:17 mammals [2] - 1434:13, 1434:17 man [1] - 1451:18 manages [1] - 1399:7 MANGES [1] - 1256:21 manipulate [2] -			

1287:11, 1326:8 manner [1] - 1346:2 Mantovani [1] - 1303:24 manufacturer [1] - 1263:11 manuscript [1] - 1428:17 March [3] - 1320:6, 1321:4, 1321:19 MARGARET [1] - 1256:12 marked [2] - 1398:14, 1431:1 market [1] - 1342:4 MARKETING [1] - 1256:4 material [3] - 1274:7, 1307:19, 1397:10 materials [13] - 1270:2, 1299:14, 1299:25, 1305:16, 1305:19, 1306:6, 1306:16, 1306:18, 1306:19, 1322:6, 1373:23, 1373:24, 1374:25 matter [20] - 1261:8, 1281:13, 1297:3, 1320:5, 1330:19, 1330:25, 1332:2, 1337:2, 1337:11, 1337:15, 1337:24, 1340:3, 1396:19, 1399:16, 1400:3, 1404:13, 1425:13, 1451:19, 1465:7, 1465:9 MATTER [1] - 1470:6 McTiernan [4] - 1275:9, 1276:1, 1421:15, 1423:15 McTiernan's [2] - 1275:5, 1423:11 MDL [1] - 1343:19 MEAGHER [1] - 1256:18 mean [16] - 1283:6, 1286:25, 1287:19, 1305:15, 1309:7, 1317:25, 1324:11, 1325:4, 1325:9, 1339:14, 1347:6, 1401:4, 1416:21, 1465:11, 1465:12, 1466:3 meaning [9] - 1272:24, 1309:5, 1318:19, 1319:4, 1401:20,	1403:2, 1418:13, 1432:24, 1433:15 meaningful [2] - 1420:20, 1421:9 means [16] - 1268:12, 1285:15, 1290:5, 1296:13, 1311:23, 1312:7, 1313:10, 1318:14, 1324:21, 1325:16, 1325:20, 1325:21, 1326:3, 1326:6, 1428:21, 1433:20 meant [3] - 1305:16, 1322:2, 1352:9 measured [1] - 1340:25 measurement [1] - 1289:6 measurements [1] - 1458:9 mechanical [1] - 1285:10 mechanism [23] - 1273:17, 1281:22, 1283:17, 1284:5, 1284:13, 1284:24, 1285:23, 1287:6, 1287:15, 1309:24, 1313:3, 1335:7, 1375:18, 1375:24, 1376:16, 1377:18, 1393:4, 1438:14, 1438:19, 1439:23, 1441:12, 1441:14, 1443:15 mechanisms [7] - 1285:6, 1304:11, 1309:14, 1313:20, 1371:9, 1375:21, 1437:7 mechanistic [5] - 1334:9, 1335:4, 1335:6, 1335:16, 1443:17 mediators [1] - 1290:14 medical [8] - 1258:23, 1284:14, 1284:16, 1321:24, 1323:12, 1339:18, 1376:23, 1450:25 Medical [1] - 1259:5 medication [1] - 1328:8 medicine [2] - 1268:21, 1307:15 Medicine [1] - 1259:9 meet [1] - 1345:14	member [1] - 1411:4 membrane [1] - 1464:17 membranes [1] - 1289:7 memory [2] - 1341:19, 1381:1 menstruation [2] - 1280:8, 1280:10 mention [2] - 1448:9, 1448:13 mentioned [10] - 1288:20, 1327:23, 1333:12, 1345:17, 1352:18, 1403:7, 1407:17, 1419:10, 1448:21, 1460:15 mentions [2] - 1357:14, 1419:18 mere [1] - 1410:1 mesothelioma [3] - 1357:15, 1357:22, 1358:5 met [1] - 1317:8 meta [29] - 1277:13, 1277:18, 1277:19, 1278:1, 1312:22, 1315:20, 1326:10, 1413:1, 1413:13, 1413:21, 1418:25, 1419:2, 1420:5, 1421:13, 1422:7, 1422:18, 1422:21, 1422:23, 1431:8, 1444:19, 1444:23, 1445:5, 1448:1, 1453:13, 1453:15, 1453:23, 1462:7 meta-analyses [13] - 1277:13, 1277:18, 1277:19, 1278:1, 1326:10, 1418:25, 1419:2, 1421:13, 1422:7, 1425:2, 1425:3, 1448:1, 1453:23 meta-analysis [16] - 1312:22, 1315:20, 1413:1, 1413:13, 1413:21, 1420:5, 1422:18, 1422:21, 1422:23, 1431:8, 1444:19, 1444:23, 1445:5, 1453:13, 1453:15, 1462:7	metal [10] - 1362:16, 1363:8, 1365:8, 1365:14, 1365:19, 1366:8, 1367:4, 1367:8, 1443:9, 1450:19 metals [43] - 1263:7, 1273:8, 1273:10, 1273:17, 1273:20, 1297:15, 1306:20, 1308:2, 1308:7, 1309:12, 1309:13, 1309:20, 1309:25, 1359:17, 1359:19, 1359:23, 1360:9, 1360:19, 1360:23, 1361:7, 1361:13, 1362:23, 1363:4, 1363:20, 1364:3, 1364:13, 1364:19, 1365:1, 1365:23, 1366:11, 1366:14, 1366:20, 1367:11, 1438:11, 1438:12, 1439:18, 1441:8, 1441:12, 1443:4, 1443:10, 1443:13, 1457:21, 1458:25 meter [3] - 1340:5, 1340:11, 1341:2 method [3] - 1311:2, 1419:4, 1454:16 methodologies [1] - 1345:25 methodology [12] - 1260:21, 1260:24, 1274:13, 1278:6, 1323:3, 1332:2, 1337:2, 1337:11, 1409:8, 1410:15, 1415:20, 1415:25 methods [5] - 1275:1, 1323:15, 1323:18, 1346:9, 1410:8 mice [2] - 1396:2, 1396:5 Mice [1] - 1452:16 MICHELLE [1] - 1256:14 microenvironment [1] - 1441:13 microphone [1] - 1277:23 microscopist [1] - 1346:20 middle [9] - 1292:17,
--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

<p>1293:10, 1293:24, 1355:4, 1374:11, 1380:1, 1381:22, 1465:23 midway [4] - 1393:25, 1394:13, 1412:9, 1437:4 might [2] - 1425:3, 1458:21 migrate [7] - 1278:24, 1279:17, 1279:20, 1281:25, 1282:5, 1369:19, 1399:8 migrates [4] - 1259:21, 1401:18, 1402:4, 1441:23 migration [11] - 1279:8, 1280:3, 1281:5, 1281:6, 1281:19, 1281:20, 1282:15, 1313:23, 1378:17, 1398:20, 1399:4 milieu [1] - 1313:5 milleau [1] - 1283:13 milliliter [1] - 1341:13 milling [1] - 1363:18 million [2] - 1329:22, 1341:13 mind [3] - 1286:24, 1356:17, 1379:20 mineral [8] - 1260:4, 1272:19, 1291:11, 1291:16, 1293:16, 1293:20, 1295:5, 1314:9 mineralogist [1] - 1339:4 mineralogy [1] - 1363:14 minerals [6] - 1268:6, 1268:8, 1270:14, 1273:1, 1286:3, 1363:21 minimum [1] - 1452:11 minimus [1] - 1333:18 mining [2] - 1363:14, 1363:18 minor [3] - 1274:10, 1283:3, 1285:17 minute [2] - 1306:25, 1443:11 minutes [4] - 1315:3, 1316:12, 1353:9, 1459:7 misstates [1] - 1298:22 mistaken [1] - 1272:18 mitotic [1] - 1386:23 model [3] - 1281:12, 1281:14, 1332:14</p>	<p>modeling [2] - 1326:19, 1327:8 moderate [1] - 1453:18 modest [10] - 1406:16, 1406:20, 1407:6, 1407:13, 1407:14, 1412:11, 1412:15, 1434:19, 1434:21, 1435:2 modulator [1] - 1296:16 molecules [1] - 1273:20 moment [11] - 1265:13, 1280:22, 1327:23, 1335:3, 1356:16, 1361:5, 1391:23, 1407:12, 1407:16, 1419:10, 1466:18 monkeys [3] - 1281:17, 1281:19, 1281:20 monograph [21] - 1272:22, 1272:25, 1340:15, 1340:19, 1340:23, 1341:17, 1341:20, 1342:16, 1342:17, 1356:6, 1356:7, 1356:15, 1356:16, 1357:7, 1358:12, 1358:14, 1370:1, 1370:3, 1370:14, 1432:4, 1434:3 monthly [1] - 1283:12 months [2] - 1318:1, 1320:6 morning [9] - 1258:5, 1258:16, 1290:25, 1317:8, 1352:6, 1352:7, 1390:14, 1454:20, 1454:24 mortality [2] - 1355:10, 1356:3 most [19] - 1277:5, 1277:6, 1277:21, 1277:24, 1306:8, 1306:11, 1306:18, 1312:14, 1312:17, 1314:22, 1319:15, 1333:21, 1349:11, 1357:2, 1383:15, 1403:19, 1404:4, 1405:15, 1442:14 mostly [5] - 1274:5, 1281:10, 1303:19, 1311:4, 1366:1</p>	<p>motile [1] - 1280:16 motility [2] - 1280:16, 1401:14 move [6] - 1271:10, 1297:4, 1297:21, 1347:20, 1430:7, 1466:20 moving [1] - 1306:5 MR [82] - 1260:12, 1264:17, 1265:10, 1266:6, 1266:17, 1267:13, 1267:24, 1268:13, 1269:8, 1269:12, 1271:5, 1271:7, 1271:11, 1275:25, 1292:16, 1293:4, 1294:8, 1294:11, 1295:16, 1295:19, 1298:18, 1299:3, 1299:10, 1299:20, 1300:8, 1317:7, 1321:16, 1327:2, 1327:6, 1329:23, 1330:1, 1332:22, 1333:13, 1336:16, 1336:18, 1344:20, 1346:14, 1347:20, 1347:23, 1348:3, 1348:4, 1350:16, 1351:19, 1351:21, 1352:20, 1353:7, 1354:9, 1357:6, 1361:22, 1364:9, 1366:16, 1368:3, 1368:25, 1371:18, 1372:14, 1374:4, 1376:24, 1377:19, 1378:21, 1381:2, 1381:17, 1382:1, 1386:18, 1395:1, 1410:18, 1411:12, 1414:12, 1414:15, 1415:8, 1416:3, 1428:8, 1428:11, 1428:16, 1431:3, 1440:3, 1442:20, 1445:14, 1459:7, 1459:12, 1461:15, 1466:21, 1467:9 MS [61] - 1258:7, 1260:16, 1260:19, 1264:23, 1265:20, 1266:1, 1266:14,</p>	<p>1266:23, 1267:18, 1268:16, 1269:2, 1269:23, 1269:25, 1270:22, 1271:18, 1272:3, 1276:2, 1276:7, 1276:18, 1276:21, 1284:11, 1292:20, 1293:13, 1294:21, 1294:23, 1295:6, 1296:7, 1297:7, 1297:9, 1297:21, 1298:23, 1299:13, 1299:23, 1300:9, 1300:11, 1300:21, 1301:14, 1301:18, 1309:19, 1315:3, 1316:9, 1332:16, 1346:4, 1372:9, 1381:25, 1428:6, 1428:10, 1440:18, 1442:23, 1443:1, 1444:21, 1453:12, 1454:6, 1454:10, 1455:12, 1456:7, 1459:4, 1466:12, 1467:10, 1467:14, 1467:20 mucociliary [1] - 1285:9 multiple [4] - 1275:18, 1296:13, 1332:9, 1371:7 multiplication [1] - 1286:11 multiplies [1] - 1286:10 multiply [1] - 1441:5 muscular [1] - 1280:12 must [3] - 1286:9, 1286:14, 1312:7 mutation [2] - 1286:8, 1286:9 mutations [2] - 1295:15, 1296:17 MY [1] - 1470:5 myriad [1] - 1451:6</p> <p>N</p> <p>name [5] - 1258:17, 1284:6, 1317:9, 1417:22, 1417:24 named [1] - 1281:18 namely [1] - 1424:10 National [2] - 1261:6, 1427:11 naturally [2] - 1363:21, 1363:23</p>
--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

near [2] - 1320:12, 1374:8	next [15] - 1274:12, 1276:20, 1288:5, 1316:15, 1337:5, 1337:6, 1353:13, 1358:21, 1414:18, 1428:14, 1430:7, 1436:18, 1463:10, 1463:18	1298:15, 1299:8, 1300:19, 1321:25, 1326:16, 1422:17, 1464:24
necessarily [5] - 1308:9, 1348:18, 1390:20, 1426:9, 1460:15		NOTES [1] - 1470:5
necessary [6] - 1308:7, 1418:15, 1423:17, 1443:8, 1443:10, 1458:2		nothing [6] - 1295:20, 1316:10, 1371:11, 1411:11, 1459:4, 1467:20
need [12] - 1308:21, 1308:22, 1319:3, 1322:16, 1333:5, 1334:4, 1334:6, 1334:8, 1335:2, 1335:16, 1361:20, 1452:2	nice [3] - 1263:11, 1333:20, 1333:24	novel [4] - 1392:19, 1392:21, 1393:4, 1393:8
needed [2] - 1308:9, 1423:20	nickel [17] - 1263:9, 1273:13, 1273:14, 1308:1, 1308:3, 1309:20, 1310:1, 1360:1, 1360:5, 1360:12, 1360:23, 1361:3, 1362:8, 1362:17, 1363:20, 1367:7, 1443:14	NTP [4] - 1396:15, 1396:18, 1396:22, 1397:2
needle [1] - 1292:6	nicotine [1] - 1458:21	nuclear [2] - 1386:9, 1386:13
needle-like [1] - 1292:6	nine [1] - 1310:24	nucleotide [1] - 1290:7
needs [3] - 1276:10, 1426:3, 1426:23	NIOSH [1] - 1258:25	number [25] - 1268:4, 1279:18, 1286:1, 1313:21, 1348:21, 1349:16, 1366:1, 1371:4, 1400:10, 1400:12, 1407:24, 1407:25, 1408:3, 1408:21, 1408:24, 1423:16, 1423:19, 1423:21, 1440:23, 1443:2, 1444:18, 1445:21, 1452:16, 1454:15, 1457:20
negative [1] - 1417:1	non [3] - 1280:16, 1364:20, 1365:2	numbers [3] - 1341:19, 1430:4, 1430:6
neogenicity [1] - 1295:23	non-motile [1] - 1280:16	numeral [2] - 1403:23, 1435:15
neoplasia [3] - 1298:17, 1387:1, 1387:4	non-users [2] - 1364:20, 1365:2	numerous [1] - 1313:2
neoplastic [12] - 1289:2, 1385:6, 1387:11, 1387:15, 1390:6, 1390:11, 1390:18, 1390:21, 1391:16, 1391:20, 1391:24, 1398:1	none [10] - 1292:16, 1292:18, 1349:24, 1359:22, 1405:4, 1415:10, 1417:24, 1418:3, 1418:10, 1456:18	Nurses' [4] - 1415:16, 1415:23, 1416:11, 1416:14
Ness [9] - 1303:20, 1304:5, 1392:6, 1392:8, 1393:10, 1454:17, 1454:18, 1454:20, 1454:21	nonetheless [1] - 1360:1	
never [5] - 1371:6, 1371:24, 1376:21, 1377:11, 1412:12	nonpapillary [1] - 1386:24	
nevertheless [1] - 1455:2	nonperineal [1] - 1456:20	
New [1] - 1427:3	nonprimate [1] - 1281:13	
NEW [4] - 1256:1, 1256:16, 1256:17, 1256:20	nonresponsive [1] - 1347:21	
new [8] - 1264:19, 1278:19, 1292:19, 1292:20, 1332:8, 1407:25, 1408:5, 1414:11	nonsignificant [4] - 1356:1, 1356:8, 1416:18, 1416:21	
newspaper [1] - 1320:19	normal [1] - 1319:5	
Newton [1] - 1279:24	notably [1] - 1280:7	
	note [1] - 1373:16	
	notebook [4] - 1260:16, 1324:1, 1326:25, 1385:17	
	noted [8] - 1280:1,	
		O
		O'DELL [62] - 1256:12, 1258:7, 1260:16, 1260:19, 1264:23, 1265:20, 1266:1, 1266:14, 1266:23, 1267:18, 1268:16, 1269:2, 1269:23, 1269:25, 1270:22, 1271:18, 1272:3, 1276:2, 1276:7, 1276:18, 1276:21, 1284:11, 1292:20, 1293:13, 1294:21,

occur [6] - 1282:14, 1286:15, 1312:8, 1322:9, 1341:25, 1363:23	1276:6, 1279:23, 1281:17, 1283:3, 1284:2, 1284:8, 1284:12, 1287:2, 1288:13, 1291:13, 1291:25, 1292:4, 1298:3, 1300:6, 1315:18, 1318:10, 1320:9, 1321:12, 1321:14, 1322:2, 1323:25, 1324:2, 1329:16, 1329:21, 1332:12, 1333:5, 1343:11, 1346:8, 1352:13, 1369:25, 1371:9, 1371:19, 1372:6, 1375:15, 1376:11, 1380:18, 1380:20, 1380:21, 1383:17, 1385:3, 1385:12, 1389:17, 1389:20, 1389:24, 1390:1, 1391:20, 1392:5, 1394:20, 1394:21, 1396:18, 1398:13, 1400:25, 1405:15, 1412:2, 1415:16, 1419:9, 1422:12, 1423:7, 1423:14, 1430:20, 1431:7, 1431:11, 1433:23, 1435:13, 1435:18, 1436:16, 1437:23, 1438:13, 1439:6, 1439:9, 1439:14, 1441:4, 1442:13, 1452:14, 1453:2, 1456:7, 1461:8, 1464:15, 1466:13	opine [2] - 1337:2, 1400:13 opined [6] - 1268:23, 1337:24, 1344:16, 1344:25, 1399:16, 1422:7 opinion [117] - 1259:15, 1262:2, 1262:18, 1262:19, 1262:21, 1263:20, 1264:19, 1274:1, 1274:8, 1276:10, 1278:23, 1279:2, 1279:16, 1281:6, 1281:21, 1282:3, 1283:20, 1285:20, 1285:21, 1286:18, 1287:25, 1295:12, 1298:1, 1301:11, 1303:15, 1307:23, 1310:7, 1310:10, 1310:11, 1313:1, 1315:13, 1315:19, 1317:18, 1317:19, 1318:9, 1320:15, 1320:24, 1322:13, 1326:1, 1326:5, 1329:17, 1330:4, 1330:9, 1331:7, 1332:1, 1333:9, 1334:15, 1336:11, 1336:21, 1337:13, 1337:19, 1338:4, 1338:8, 1338:18, 1338:24, 1339:13, 1339:18, 1343:23, 1344:2, 1345:14, 1346:22, 1347:11, 1348:5, 1348:6, 1349:5, 1359:18, 1361:16, 1361:20, 1362:1, 1367:10, 1367:11, 1370:17, 1374:10, 1379:23, 1383:5, 1384:9, 1384:11, 1400:7, 1400:8, 1400:10, 1400:21, 1403:13, 1403:15, 1403:21, 1404:8, 1405:12, 1406:2, 1406:9, 1411:20, 1414:5, 1418:19, 1418:20, 1420:18, 1420:23, 1421:8,	1421:11, 1421:12, 1421:14, 1430:23, 1443:19, 1444:6, 1444:14, 1444:17, 1449:1, 1449:9, 1449:24, 1450:8, 1451:11, 1451:15, 1451:16, 1451:17, 1455:9, 1455:12, 1458:2, 1458:24, 1459:3, 1466:24 opinions [45] - 1259:14, 1260:20, 1260:24, 1269:19, 1276:14, 1282:18, 1288:7, 1288:11, 1291:7, 1292:21, 1298:4, 1301:20, 1317:10, 1327:22, 1329:9, 1346:13, 1348:14, 1367:20, 1373:22, 1374:2, 1375:8, 1375:12, 1375:16, 1378:11, 1389:25, 1390:2, 1395:19, 1398:24, 1402:19, 1403:2, 1408:21, 1417:16, 1417:19, 1418:23, 1418:24, 1419:3, 1422:6, 1443:8, 1449:7, 1449:17, 1451:20, 1452:1, 1452:4, 1456:4, 1456:5 opportunity [3] - 1276:11, 1305:8, 1398:11 opposed [2] - 1352:9, 1410:1 Opposition [1] - 1444:21 opposition [1] - 1445:20 oral [1] - 1398:12 orangeish [1] - 1306:23 order [17] - 1286:15, 1308:7, 1333:6, 1335:1, 1335:18, 1355:21, 1359:14, 1409:24, 1426:4, 1426:7, 1426:16, 1426:24, 1452:3, 1465:5, 1465:21, 1465:23, 1467:7 ore [1] - 1264:2 organ [1] - 1285:16
old [1] - 1318:11 once [8] - 1287:7, 1296:11, 1302:18, 1305:4, 1461:19, 1464:15, 1464:19, 1465:1 oncologist [1] - 1377:9 oncologists [1] - 1404:23 One [1] - 1467:10 one [92] - 1261:6, 1266:3, 1267:6, 1269:8, 1269:9, 1270:4, 1271:19, 1275:10	one-page [1] - 1452:14 ones [1] - 1349:19 oophorectomies [1] - 1372:3 open [7] - 1258:3, 1279:4, 1283:9, 1399:11, 1400:19, 1400:22, 1440:9 operate [4] - 1309:15, 1438:14, 1438:19, 1439:23 operates [1] - 1457:15 operations [1] - 1363:15	1367:10, 1367:11, 1370:17, 1374:10, 1379:23, 1383:5, 1384:9, 1384:11, 1400:7, 1400:8, 1400:10, 1400:21, 1403:13, 1403:15, 1403:21, 1404:8, 1405:12, 1406:2, 1406:9, 1411:20, 1414:5, 1418:19, 1418:20, 1420:18, 1420:23, 1421:8,	1276:11, 1305:8, 1398:11 1410:1 Opposition [1] - 1444:21 opposition [1] - 1445:20 oral [1] - 1398:12 orangeish [1] - 1306:23 order [17] - 1286:15, 1308:7, 1333:6, 1335:1, 1335:18, 1355:21, 1359:14, 1409:24, 1426:4, 1426:7, 1426:16, 1426:24, 1452:3, 1465:5, 1465:21, 1465:23, 1467:7 ore [1] - 1264:2 organ [1] - 1285:16

organic [1] - 1274:5 organisms [1] - 1323:10 organization [1] - 1436:8 organizations [2] - 1282:13, 1427:10 organs [2] - 1285:19, 1308:15 oriented [1] - 1346:1 original [2] - 1326:8, 1326:9 outline [1] - 1258:19 outlined [1] - 1293:1 outside [7] - 1285:5, 1339:12, 1339:16, 1399:12, 1399:17, 1399:22, 1400:20 Ovarian [1] - 1452:15 ovarian [144] - 1259:20, 1260:11, 1274:18, 1277:1, 1277:5, 1280:21, 1282:4, 1282:12, 1283:17, 1284:4, 1286:20, 1288:15, 1289:24, 1290:3, 1298:15, 1303:9, 1303:11, 1303:18, 1304:2, 1304:12, 1308:5, 1308:10, 1309:8, 1309:9, 1309:12, 1310:12, 1310:13, 1311:8, 1312:1, 1313:4, 1313:7, 1313:24, 1314:4, 1314:11, 1314:16, 1315:16, 1315:25, 1316:3, 1316:8, 1317:15, 1317:20, 1317:21, 1329:14, 1329:19, 1329:21, 1329:22, 1330:6, 1330:11, 1331:5, 1331:21, 1335:8, 1335:14, 1336:8, 1336:13, 1336:15, 1336:23, 1337:4, 1339:20, 1339:22, 1343:24, 1344:3, 1346:22, 1348:23, 1349:14, 1351:9, 1355:15, 1356:2, 1358:19, 1360:6, 1360:14, 1368:16, 1376:21,	1377:3, 1377:6, 1377:12, 1381:10, 1383:6, 1383:21, 1384:10, 1384:13, 1384:15, 1384:17, 1385:25, 1386:5, 1387:19, 1388:22, 1389:18, 1392:2, 1393:3, 1394:1, 1394:4, 1394:19, 1396:10, 1397:11, 1397:21, 1403:18, 1404:3, 1405:12, 1406:4, 1406:10, 1406:24, 1407:25, 1408:6, 1408:10, 1409:21, 1411:22, 1412:11, 1413:3, 1414:1, 1414:7, 1415:13, 1415:22, 1416:8, 1420:19, 1422:19, 1424:25, 1426:21, 1427:25, 1435:1, 1437:16, 1438:14, 1439:24, 1443:16, 1444:1, 1445:1, 1446:1, 1447:25, 1452:12, 1453:21, 1454:1, 1455:3, 1455:8, 1457:4, 1459:2, 1459:22, 1460:2, 1460:13, 1460:25, 1462:9, 1467:18 ovaries [77] - 1259:23, 1278:25, 1279:6, 1279:9, 1279:17, 1280:5, 1282:1, 1282:14, 1282:24, 1283:7, 1284:5, 1285:14, 1285:22, 1300:15, 1301:5, 1305:2, 1305:3, 1308:8, 1309:15, 1328:25, 1335:25, 1357:22, 1358:8, 1364:4, 1364:7, 1364:8, 1364:13, 1364:17, 1366:15, 1369:12, 1369:15, 1369:19, 1369:23, 1370:24, 1370:25,	1371:5, 1371:16, 1371:23, 1372:3, 1372:7, 1373:17, 1376:5, 1376:8, 1383:25, 1386:25, 1387:13, 1388:12, 1388:25, 1394:22, 1396:5, 1396:15, 1397:3, 1397:6, 1397:11, 1401:2, 1401:18, 1402:4, 1403:25, 1404:2, 1404:9, 1405:2, 1406:4, 1406:10, 1406:24, 1407:25, 1408:6, 1408:10, 1409:21, 1411:22, 1412:11, 1413:3, 1414:1, 1414:7, 1415:13, 1415:22, 1416:8, 1420:19, 1422:19, 1424:25, 1426:21, 1427:25, 1435:1, 1437:16, 1438:14, 1439:24, 1443:16, 1444:1, 1445:1, 1446:1, 1447:25, 1452:12, 1453:21, 1454:1, 1455:3, 1455:8, 1457:4, 1459:2, 1459:22, 1460:2, 1460:13, 1460:25, 1462:9, 1467:18 ovary [26] - 1283:5, 1283:8, 1283:10, 1283:13, 1283:21, 1284:23, 1336:9, 1339:21, 1355:9, 1357:16, 1359:24, 1361:19, 1367:3, 1370:13, 1387:1, 1396:7, 1398:9, 1444:9, 1444:12, 1452:3, 1452:20, 1453:7, 1464:10, 1465:1, 1465:3 overall [4] - 1274:9, 1359:13, 1415:12, 1462:12 overlapping [3] - 1288:17, 1290:20, 1420:4 ovulates [1] - 1283:8 ovulation [1] - 1314:3 own [11] - 1262:11, 1276:10, 1278:11, 1342:25, 1344:19, 1404:20, 1411:2, 1423:15, 1438:5, 1466:1, 1466:18 oxidative [9] - 1289:6, 1289:17, 1377:25, 1378:1, 1378:6, 1378:8, 1402:21, 1403:5, 1437:8 oxide [5] - 1450:19, 1450:25, 1451:3, 1451:7	oxygen [10] - 1273:23, 1289:4, 1289:8, 1290:2, 1290:15, 1296:15, 1319:4, 1319:6 P P-256 [2] - 1381:16, 1382:1 P-264 [1] - 1383:10 p.m [1] - 1467:23 pack [1] - 1458:12 page [127] - 1266:17, 1267:14, 1293:18, 1293:24, 1293:25, 1294:16, 1295:18, 1296:9, 1296:10, 1300:23, 1301:13, 1301:14, 1301:17, 1316:15, 1321:18, 1321:23, 1324:5, 1324:25, 1325:12, 1327:3, 1329:23, 1330:1, 1333:15, 1336:18, 1340:20, 1340:23, 1341:17, 1341:18, 1343:2, 1344:22, 1344:23, 1345:6, 1345:8, 1350:18, 1351:21, 1352:22, 1353:13, 1355:3, 1355:4, 1357:9, 1361:24, 1364:11, 1366:18, 1368:5, 1369:2, 1372:17, 1372:18, 1373:2, 1373:8, 1374:11, 1374:12, 1374:18, 1375:2, 1377:21, 1378:23, 1379:25, 1380:1, 1381:4, 1381:21, 1382:15, 1382:18, 1383:7, 1383:8, 1386:16, 1388:7, 1391:1, 1391:9, 1392:24, 1393:24, 1394:11, 1395:20, 1397:8, 1402:2, 1402:12, 1403:13, 1403:22, 1410:20, 1411:14, 1412:8, 1412:25, 1413:10, 1413:18, 1414:18, 1416:5, 1418:7, 1418:8,
-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

1419:13, 1419:14, 1422:16, 1427:20, 1428:10, 1428:15, 1429:7, 1429:10, 1431:11, 1431:17, 1433:10, 1434:23, 1435:14, 1437:2, 1440:24, 1441:21, 1442:5, 1444:23, 1446:9, 1446:11, 1446:22, 1447:10, 1452:14, 1454:9, 1454:21, 1455:1, 1456:13, 1456:14, 1461:16, 1463:4, 1463:7, 1463:8, 1463:10, 1463:11, 1465:23 Page [1] - 1468:5 pages [8] - 1373:25, 1374:14, 1377:1, 1395:7, 1418:4, 1418:5, 1428:12, 1447:8 paid [1] - 1444:24 paper [34] - 1265:1, 1265:23, 1265:25, 1266:1, 1270:1, 1284:2, 1284:6, 1284:12, 1392:8, 1392:15, 1393:1, 1393:10, 1393:13, 1393:14, 1393:15, 1393:18, 1394:11, 1394:16, 1410:7, 1414:2, 1417:15, 1434:4, 1448:4, 1448:9, 1448:12, 1448:13, 1448:21, 1448:24, 1454:17, 1454:18, 1454:21, 1455:1, 1466:4, 1466:7 paper's [1] - 1417:17 papers [7] - 1270:10, 1325:8, 1348:17, 1392:5, 1446:24, 1447:2, 1466:1 papillae [2] - 1298:17, 1464:24 papillary [10] - 1298:16, 1300:19, 1301:4, 1386:4, 1386:8, 1387:25, 1388:2, 1388:5, 1388:11,	1389:11 paragraph [23] - 1293:25, 1294:13, 1325:14, 1355:4, 1357:10, 1357:25, 1358:21, 1381:23, 1386:17, 1386:21, 1388:8, 1391:1, 1394:13, 1395:20, 1397:9, 1398:5, 1398:17, 1403:22, 1413:11, 1433:10, 1437:4, 1437:23 PARFITT [1] - 1256:14 Park [3] - 1320:7, 1320:13, 1320:16 part [26] - 1264:9, 1265:7, 1270:2, 1299:5, 1299:14, 1299:25, 1304:7, 1309:25, 1337:18, 1337:22, 1338:20, 1340:14, 1346:25, 1347:8, 1349:11, 1376:5, 1376:7, 1386:18, 1396:15, 1423:9, 1428:14, 1438:23, 1443:17, 1444:25, 1453:6, 1459:17 Part [1] - 1433:11 partial [1] - 1319:5 participate [2] - 1309:22, 1361:8 participates [2] - 1287:2, 1315:9 particle [1] - 1281:2 particles [11] - 1279:8, 1279:25, 1280:3, 1280:23, 1282:19, 1285:1, 1285:5, 1373:18, 1400:14, 1401:14, 1404:1 particular [24] - 1264:21, 1266:9, 1275:21, 1294:16, 1297:22, 1301:3, 1304:4, 1304:8, 1311:9, 1312:1, 1313:1, 1322:12, 1324:16, 1327:19, 1332:4, 1427:20, 1439:19, 1441:12, 1444:3, 1447:18, 1451:25, 1452:21, 1460:25,	1461:6 particularly [2] - 1295:4, 1395:4 particulate [6] - 1279:20, 1382:14, 1382:19, 1382:22, 1404:13, 1448:19 particulates [5] - 1279:8, 1280:24, 1280:25, 1282:5, 1448:20 parts [7] - 1305:5, 1320:12, 1358:14, 1370:21, 1376:1, 1383:16, 1404:14 passages [1] - 1440:23 passing [1] - 1292:6 past [1] - 1259:6 pathologist [1] - 1377:14 pathway [2] - 1295:11, 1313:23 pathways [1] - 1286:1 patient [2] - 1377:11, 1451:21 patients [6] - 1268:5, 1302:23, 1372:24, 1376:21, 1377:3, 1451:6 pause [3] - 1260:18, 1372:15, 1394:9 Pause [1] - 1271:6 Pearson [1] - 1279:14 peer [4] - 1271:1, 1323:2, 1428:20, 1436:25 peer-reviewed [4] - 1271:1, 1323:2, 1428:20, 1436:25 Penninkilampi [16] - 1275:22, 1276:22, 1276:24, 1312:22, 1315:18, 1419:11, 1419:16, 1420:6, 1448:2, 1454:4, 1456:10, 1456:15, 1459:14, 1460:5, 1460:23, 1461:5 people [6] - 1310:14, 1322:5, 1345:23, 1411:6, 1442:14, 1452:12 per [9] - 1320:12, 1340:5, 1340:11, 1341:1, 1341:13, 1398:10, 1408:8, 1409:21 percent [11] - 1259:20,	1275:17, 1277:9, 1368:1, 1406:10, 1408:7, 1408:18, 1409:19, 1410:4, 1429:5, 1450:16 perform [4] - 1310:4, 1366:25, 1421:7, 1465:19 performed [9] - 1261:24, 1274:21, 1275:12, 1275:23, 1277:14, 1277:20, 1366:24, 1396:7, 1421:13 perhaps [2] - 1291:17, 1349:23 perineal [38] - 1277:15, 1279:5, 1280:20, 1282:11, 1283:2, 1315:24, 1317:14, 1317:19, 1328:11, 1330:10, 1331:20, 1336:1, 1341:24, 1349:25, 1351:7, 1351:24, 1394:19, 1398:11, 1398:20, 1399:10, 1399:17, 1399:18, 1399:22, 1401:18, 1402:4, 1406:3, 1408:14, 1411:21, 1415:13, 1424:24, 1427:25, 1433:3, 1434:25, 1437:15, 1441:24, 1459:21, 1463:20 perineally [4] - 1330:20, 1331:1, 1335:22, 1376:3 perineum [8] - 1259:22, 1278:24, 1279:9, 1282:6, 1282:14, 1399:7, 1399:13, 1403:8 period [8] - 1286:16, 1286:17, 1286:19, 1286:21, 1318:1, 1450:6, 1452:8, 1460:21 periods [1] - 1288:17 peristaltic [1] - 1280:12 peritoneal [2] - 1280:5, 1282:6 peritoneum [1] - 1399:6 permission [21] - 1271:22, 1327:2, 1329:23, 1333:13, 1336:16, 1344:20,
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1350:16, 1351:19, 1352:20, 1361:22, 1364:9, 1366:16, 1368:3, 1368:25, 1376:24, 1377:19, 1378:21, 1381:2, 1410:18, 1411:12, 1416:3 permit [2] - 1346:7, 1465:14 permitted [1] - 1466:11 peroxidation [1] - 1289:17 person [5] - 1324:17, 1329:21, 1341:4, 1431:12, 1451:25 Personal [1] - 1257:6 personal [6] - 1262:12, 1317:14, 1320:5, 1328:4, 1345:3, 1450:12 personally [1] - 1344:6 perspective [1] - 1440:22 pertinent [2] - 1288:10, 1440:22 petrochemical [1] - 1320:8 Ph.D [3] - 1259:7, 1259:11, 1284:16 phenomenon [1] - 1377:25 photo [20] - 1265:5, 1265:8, 1265:15, 1265:17, 1265:24, 1266:2, 1266:5, 1267:9, 1268:25, 1269:7, 1270:16, 1270:22, 1271:10, 1272:1, 1272:5, 1272:6, 1291:20, 1292:3, 1292:11, 1295:9 photograph [4] - 1265:11, 1292:17, 1293:10 photographs [2] - 1264:20, 1271:13 photos [5] - 1271:2, 1271:23, 1292:23, 1294:3 phrase [3] - 1404:17, 1420:24, 1430:19 phrased [1] - 1410:10 physician [4] - 1258:22,	1307:15, 1310:20, 1377:7 physicist [1] - 1465:16 physiological [1] - 1398:15 picked [2] - 1420:6, 1445:16 picking [1] - 1418:21 picture [1] - 1265:3 pictures [2] - 1264:14, 1302:5 pieces [4] - 1271:20, 1332:8, 1332:9, 1409:20 pierced [1] - 1464:15 place [3] - 1322:1, 1322:4, 1411:25 placed [1] - 1463:2 places [4] - 1266:16, 1308:23, 1356:23, 1370:22 plaintiff [1] - 1337:24 plaintiff's [1] - 1338:5 Plaintiffs [2] - 1256:14, 1258:11 plaintiffs [8] - 1268:24, 1342:23, 1365:18, 1366:6, 1396:19, 1444:22, 1445:19, 1454:11 plaintiffs' [2] - 1343:12, 1431:6 planning [1] - 1268:3 plans [1] - 1344:11 plant [2] - 1320:8, 1322:7 platy [18] - 1262:18, 1262:19, 1262:25, 1264:5, 1264:14, 1264:25, 1265:3, 1265:4, 1265:9, 1265:14, 1265:18, 1265:21, 1266:9, 1266:12, 1269:4, 1270:24, 1272:9, 1306:9 plausibility [10] - 1282:10, 1296:10, 1312:25, 1313:9, 1313:14, 1314:22, 1375:17, 1376:2, 1399:2, 1459:1 plausible [4] - 1443:15, 1443:20, 1444:15, 1448:4 pleurodesis [1] -	1302:19 plot [5] - 1275:4, 1275:5, 1275:6, 1278:12, 1311:12 plume [1] - 1322:19 point [21] - 1265:20, 1270:13, 1288:12, 1288:19, 1294:15, 1300:3, 1307:22, 1311:14, 1323:5, 1334:10, 1342:14, 1350:2, 1354:11, 1365:4, 1392:20, 1393:16, 1397:14, 1430:1, 1458:19, 1464:25, 1466:22 pointed [4] - 1293:10, 1294:14, 1462:15, 1464:5 pointer [1] - 1292:8 points [2] - 1302:8, 1398:17 poison [2] - 1318:11, 1333:2 poisoning [1] - 1319:6 polite [1] - 1442:24 polymorphisms [1] - 1290:7 pooled [7] - 1277:14, 1277:18, 1278:3, 1412:6, 1453:15, 1453:24, 1456:23 Popkin [1] - 1398:4 POPKIN [1] - 1256:20 population [4] - 1318:22, 1322:21, 1341:8, 1460:19 porosity [1] - 1382:6 portion [8] - 1282:20, 1282:22, 1301:16, 1378:9, 1386:20, 1390:21, 1401:10, 1467:7 portions [2] - 1376:2, 1440:22 pose [1] - 1259:16 position [1] - 1401:6 positive [17] - 1259:18, 1275:14, 1277:4, 1278:1, 1278:14, 1278:15, 1311:16, 1313:14, 1355:10, 1356:1, 1416:18,	1416:21, 1416:22, 1425:6, 1429:20, 1430:3, 1453:25 possibilities [2] - 1371:11, 1389:17 possibility [3] - 1309:6, 1331:10, 1369:21 possible [12] - 1272:24, 1273:15, 1319:12, 1388:24, 1417:13, 1418:2, 1418:12, 1433:1, 1435:7, 1437:7, 1437:15, 1439:6 possibly [5] - 1340:13, 1389:8, 1432:13, 1433:3, 1435:15 potency [8] - 1291:17, 1305:14, 1305:18, 1306:6, 1306:20, 1306:22, 1314:13, 1359:20 potent [1] - 1306:14 potential [25] - 1259:25, 1261:11, 1263:25, 1282:5, 1282:25, 1287:13, 1303:18, 1305:3, 1306:5, 1306:9, 1306:15, 1306:19, 1307:1, 1308:12, 1309:16, 1334:11, 1339:22, 1348:10, 1348:18, 1358:15, 1360:20, 1382:5, 1396:6, 1435:3, 1452:20 potentially [2] - 1409:22, 1449:3 Powder [16] - 1259:16, 1260:3, 1260:8, 1260:10, 1262:16, 1262:22, 1262:24, 1263:2, 1263:22, 1264:24, 1273:9, 1274:2, 1274:12, 1380:2, 1433:11, 1443:5 POWDER [1] - 1256:4 powder [164] - 1259:20, 1259:25, 1263:5, 1263:17, 1274:10, 1277:15, 1278:20, 1278:24, 1279:16, 1280:25, 1281:2, 1281:25, 1282:16, 1282:19, 1282:20,
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1283:5, 1283:7, 1284:22, 1285:21, 1286:19, 1286:21, 1287:23, 1288:1, 1288:3, 1289:25, 1290:10, 1290:11, 1290:18, 1290:22, 1291:1, 1292:22, 1293:19, 1296:12, 1297:16, 1298:1, 1301:21, 1301:25, 1302:3, 1304:21, 1305:11, 1306:9, 1307:2, 1310:12, 1312:3, 1312:10, 1313:8, 1313:15, 1314:15, 1315:7, 1315:8, 1315:15, 1316:2, 1316:7, 1317:14, 1317:20, 1318:4, 1326:7, 1326:20, 1327:9, 1327:19, 1327:20, 1328:3, 1329:13, 1329:18, 1329:20, 1330:6, 1330:10, 1331:6, 1331:16, 1331:20, 1332:25, 1333:7, 1333:22, 1335:2, 1335:8, 1335:24, 1336:7, 1336:13, 1336:23, 1337:3, 1338:25, 1342:4, 1342:7, 1342:13, 1342:21, 1343:6, 1343:14, 1343:17, 1343:20, 1343:23, 1343:25, 1344:3, 1346:22, 1346:24, 1347:2, 1347:4, 1347:7, 1348:6, 1348:12, 1348:22, 1349:1, 1350:1, 1350:12, 1350:24, 1352:16, 1353:1, 1359:19, 1362:23, 1363:5, 1365:9, 1365:14, 1365:20, 1365:23, 1366:12, 1366:21, 1367:23, 1368:8, 1368:18, 1369:11, 1370:5, 1371:6, 1376:3, 1378:13, 1384:21,	1385:25, 1396:20, 1396:23, 1400:14, 1400:15, 1400:18, 1401:17, 1401:19, 1402:3, 1403:20, 1406:11, 1407:20, 1408:4, 1408:11, 1409:22, 1412:10, 1412:12, 1413:14, 1414:1, 1414:6, 1415:13, 1434:25, 1441:23, 1442:9, 1443:9, 1443:16, 1443:21, 1443:24, 1444:8, 1444:15, 1446:2, 1446:7, 1452:2, 1454:1, 1457:4, 1457:22, 1458:5, 1464:20, 1465:2, 1467:18 powders [1] - 1259:19 power [16] - 1420:14, 1420:20, 1421:4, 1421:7, 1421:9, 1421:18, 1422:4, 1422:11, 1422:20, 1422:24, 1423:15, 1423:17, 1423:25, 1424:3, 1437:15 PowerPoint [6] - 1300:22, 1301:8, 1445:7, 1445:9, 1445:12, 1453:12 practice [3] - 1258:24, 1261:4, 1284:19 practices [1] - 1402:1 PRACTICES [1] - 1256:5 preamble [2] - 1428:4, 1433:22 precancer [2] - 1387:5, 1387:7 precautionary [9] - 1322:19, 1425:16, 1425:20, 1426:11, 1426:19, 1426:25, 1427:8, 1457:10, 1457:16 precept [3] - 1425:20, 1425:24, 1426:2 precise [1] - 1330:23 predict [1] - 1335:13 preface [1] - 1339:14 preparation [3] -	1418:14, 1428:22, 1446:14 prepare [1] - 1305:22 prepared [5] - 1264:13, 1425:12, 1435:13, 1445:8, 1446:4 preparing [4] - 1329:9, 1374:16, 1417:10, 1449:8 prescription [1] - 1328:8 presence [14] - 1263:20, 1264:2, 1264:4, 1271:21, 1284:3, 1304:16, 1305:13, 1359:18, 1443:13, 1443:23, 1453:5, 1455:16, 1455:23, 1458:25 present [18] - 1263:4, 1283:13, 1297:1, 1306:13, 1306:16, 1306:21, 1306:25, 1311:6, 1363:10, 1363:25, 1368:23, 1373:17, 1383:16, 1388:22, 1389:2, 1392:22, 1431:6, 1451:19 presentation [10] - 1268:18, 1375:20, 1390:14, 1431:5, 1431:16, 1431:17, 1436:10, 1445:13, 1454:19, 1459:17 presented [4] - 1326:13, 1334:1, 1410:7, 1447:15 presenting [1] - 1392:11 pressed [1] - 1347:19 pressure [1] - 1319:5 pretty [5] - 1281:15, 1400:1, 1400:2, 1400:20, 1425:4 prevalence [1] - 1408:4 prevented [2] - 1334:1, 1409:22 preventive [1] - 1426:17 prevents [2] - 1302:24, 1314:3 previous [2] - 1327:1, 1408:17 primarily [3] - 1268:6, 1273:21, 1352:1 primary [5] - 1311:1,	1313:3, 1327:14, 1351:16, 1392:11 principal [1] - 1328:17 principle [8] - 1425:17, 1425:20, 1426:11, 1426:23, 1438:25, 1457:10, 1457:16, 1458:14 principles [1] - 1427:9 prison [1] - 1450:2 probable [2] - 1432:16, 1439:6 problem [8] - 1263:23, 1265:16, 1269:7, 1272:1, 1426:13, 1426:14, 1452:11 problems [1] - 1396:24 procedure [1] - 1372:6 procedures [1] - 1359:14 proceeding [3] - 1343:19, 1427:2, 1427:6 Proceedings [1] - 1468:5 proceedings [1] - 1400:5 process [13] - 1261:5, 1283:11, 1286:4, 1286:5, 1286:24, 1287:9, 1308:1, 1308:15, 1308:18, 1376:11, 1389:18, 1437:6, 1443:18 produce [9] - 1285:22, 1286:7, 1302:19, 1305:8, 1306:10, 1306:15, 1314:16, 1318:21, 1452:11 produced [4] - 1262:10, 1264:9, 1280:12, 1302:15 produces [5] - 1260:1, 1263:23, 1302:10, 1318:20, 1376:7 producing [3] - 1291:21, 1303:6, 1315:9 product [15] - 1263:11, 1293:3, 1305:15, 1306:11, 1306:21, 1307:6, 1327:20, 1331:16, 1352:17, 1366:8, 1426:4, 1444:12, 1445:1, 1445:4, 1457:24 product's [1] - 1339:2 production [3] - 1313:3,
------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

<p>1449:2, 1450:3 PRODUCTS [1] - 1256:4 products [42] - 1263:17, 1268:19, 1278:21, 1285:21, 1291:2, 1306:14, 1315:7, 1317:20, 1329:13, 1329:18, 1330:6, 1336:7, 1336:13, 1336:23, 1338:25, 1342:4, 1342:8, 1342:13, 1342:14, 1342:21, 1343:14, 1343:17, 1343:21, 1343:25, 1344:8, 1346:24, 1347:2, 1347:5, 1348:6, 1348:23, 1349:2, 1350:1, 1365:9, 1365:14, 1367:16, 1368:11, 1406:11, 1444:8, 1444:9, 1444:15, 1457:22, 1458:22 Products [1] - 1257:6 professional [4] - 1258:24, 1261:4, 1268:10, 1370:20 professionally [2] - 1378:2, 1410:13 Professor [1] - 1258:21 Program [2] - 1258:25, 1259:5 program [1] - 1259:4 programmed [1] - 1289:19 progressed [1] - 1451:13 proliferation [4] - 1260:7, 1289:2, 1290:4, 1293:22 promotes [1] - 1455:7 promotion [6] - 1286:12, 1286:15, 1287:3, 1296:17, 1297:12, 1315:11 pronunciation [1] - 1428:3 proof [1] - 1282:4 proper [2] - 1323:3, 1330:14 properties [3] - 1302:17, 1303:1, 1382:5 proportion [1] - 1301:5</p>	<p>proposed [5] - 1273:17, 1284:4, 1313:21, 1371:9, 1375:21 proposes [2] - 1392:18, 1393:3 proposition [6] - 1380:19, 1381:7, 1390:10, 1390:17, 1405:8, 1412:3 PROSKAUER [1] - 1256:19 prospective [3] - 1415:11, 1416:6, 1416:17 protection [1] - 1450:12 protective [2] - 1322:5, 1393:3 prove [1] - 1393:11 proven [1] - 1426:14 provide [4] - 1393:18, 1443:14, 1446:6, 1447:3 provided [6] - 1262:9, 1346:11, 1403:3, 1431:5, 1449:21, 1450:12 provides [3] - 1437:6, 1443:17, 1453:3 providing [1] - 1285:23 pubic [1] - 1399:14 Public [3] - 1258:22, 1321:24, 1411:6 public [1] - 1427:10 publication [5] - 1272:7, 1272:8, 1304:8, 1324:2, 1456:14 publications [6] - 1274:25, 1323:2, 1323:5, 1323:25, 1374:21, 1375:7 publish [1] - 1436:9 published [15] - 1262:7, 1268:7, 1272:25, 1289:22, 1310:25, 1325:8, 1327:24, 1410:7, 1425:8, 1427:14, 1427:16, 1428:19, 1447:19, 1447:24, 1455:22 pull [4] - 1321:13, 1448:4, 1453:12, 1461:15 pulled [2] - 1302:7, 1383:10</p>	<p>pump [1] - 1280:12 pure [2] - 1262:18, 1262:19 purport [1] - 1393:18 purported [1] - 1304:10 purportedly [1] - 1335:8 purpose [10] - 1281:15, 1303:1, 1359:9, 1359:13, 1393:13, 1393:14, 1393:15, 1409:4, 1448:23 purposes [11] - 1261:3, 1268:14, 1281:6, 1288:11, 1312:4, 1326:1, 1326:5, 1343:19, 1359:8, 1409:8, 1411:18 PURSUANT [1] - 1470:3 pushing [1] - 1285:10 put [15] - 1270:14, 1271:3, 1271:10, 1287:13, 1300:9, 1310:15, 1372:17, 1378:7, 1380:20, 1388:1, 1395:5, 1410:13, 1428:6, 1428:11, 1451:10</p>	<p>Q</p>	<p>quadrant [3] - 1306:2, 1306:12, 1306:17 qualifications [1] - 1258:20 qualitative [2] - 1350:14, 1352:19 quality [1] - 1275:2 quantifiable [2] - 1324:23, 1325:5 quantification [1] - 1343:18 quantified [6] - 1329:4, 1329:6, 1329:8, 1343:13, 1365:18, 1366:7 quantify [8] - 1325:17, 1326:15, 1326:17, 1342:19, 1343:5, 1343:16, 1365:7, 1365:13 quantitation [1] - 1369:23 quantities [5] - 1307:1, 1347:15, 1363:10, 1368:10, 1399:25 quantity [13] - 1304:21, 1306:16, 1326:20, 1327:9, 1328:3, 1328:11, 1347:3, 1351:17, 1363:1, 1368:17, 1368:19, 1373:4, 1454:16 QUESTION [35] - 1295:22, 1296:1, 1327:8, 1330:4, 1333:17, 1334:4, 1336:21, 1343:4, 1350:20, 1351:3, 1351:23, 1352:23, 1361:25, 1364:12, 1366:19, 1368:6, 1369:3, 1377:2, 1377:22, 1378:24, 1379:4, 1379:8, 1379:11, 1381:6, 1402:3, 1410:21, 1410:24, 1411:15, 1416:6, 1416:10, 1416:15, 1441:2, 1441:7, 1441:23, 1442:6 questioning [2] - 1448:10, 1448:11 questions [44] - 1267:20, 1267:22, 1267:25, 1269:23, 1300:7, 1316:9, 1317:9, 1352:6, 1359:16, 1361:12, 1362:15, 1372:10, 1379:16, 1399:1, 1405:22, 1415:10, 1440:3, 1443:2, 1443:6, 1444:18, 1445:9, 1445:21, 1447:8, 1447:12, 1448:8, 1449:4, 1449:19, 1449:22, 1451:23, 1451:25, 1452:13, 1452:17, 1452:19, 1452:22, 1453:16, 1453:19, 1454:18, 1455:14, 1455:17, 1456:12, 1457:20, 1464:1, 1467:9, 1467:15 quick [1] - 1341:17 quickly [4] - 1297:8, 1369:8, 1438:9, 1465:21</p>
------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-----------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

<p>quite [3] - 1273:19, 1274:4, 1440:21 quotation [2] - 1298:3, 1356:5 quotations [1] - 1322:24 quote [7] - 1298:11, 1322:10, 1355:7, 1357:13, 1381:24, 1466:1, 1466:4 quoted [3] - 1320:19, 1356:12, 1465:25 quotes [2] - 1298:23, 1298:24 quoting [3] - 1356:7, 1436:10, 1438:17</p>	<p>rational [1] - 1375:20 rationale [1] - 1434:24 ratios [3] - 1275:14, 1313:14, 1425:6 Rats [1] - 1452:16 rats [25] - 1298:15, 1383:18, 1384:3, 1384:20, 1385:7, 1385:25, 1386:3, 1387:10, 1387:22, 1389:6, 1389:12, 1392:3, 1396:1, 1396:2, 1396:5, 1396:11, 1396:15, 1396:22, 1397:3, 1397:11, 1397:22, 1398:19, 1452:24, 1453:8, 1464:5 rats' [1] - 1383:24 ray [1] - 1272:10 RE [1] - 1256:4 reach [8] - 1278:24, 1310:7, 1316:2, 1371:16, 1421:8, 1443:8, 1444:9, 1444:12 reached [9] - 1262:1, 1281:24, 1282:3, 1320:12, 1366:15, 1452:3, 1457:17, 1461:14, 1461:18 reaches [10] - 1328:25, 1335:25, 1364:4, 1364:7, 1364:8, 1364:13, 1364:17, 1369:15, 1404:2, 1444:5 reaching [13] - 1260:24, 1279:16, 1281:6, 1288:7, 1288:11, 1296:11, 1301:20, 1303:15, 1309:25, 1370:13, 1375:7, 1375:16, 1449:6 reaction [6] - 1379:15, 1380:8, 1384:7, 1391:4, 1391:15, 1391:20 reactions [5] - 1273:22, 1302:10, 1309:23, 1361:9, 1373:12 reactive [6] - 1273:23, 1289:3, 1289:8, 1290:2, 1290:15, 1296:15 read [51] - 1266:7, 1303:14, 1322:24, 1327:2, 1329:23,</p>	<p>1333:13, 1336:16, 1344:20, 1345:11, 1350:16, 1351:19, 1352:20, 1357:17, 1357:18, 1358:6, 1358:25, 1361:22, 1364:9, 1366:16, 1368:3, 1368:25, 1373:14, 1376:24, 1377:19, 1378:21, 1381:2, 1382:8, 1391:17, 1394:7, 1398:4, 1398:16, 1404:6, 1410:18, 1411:12, 1413:16, 1416:3, 1421:25, 1423:11, 1424:12, 1435:5, 1435:24, 1437:2, 1437:11, 1437:19, 1440:20, 1440:23, 1441:21, 1441:22, 1442:21, 1462:19, 1462:22 reading [4] - 1293:14, 1301:13, 1327:7, 1422:4 Reading [3] - 1330:3, 1336:20, 1351:22 reads [2] - 1381:23, 1382:3 ready [1] - 1279:5 realistic [1] - 1425:3 realized [2] - 1291:4, 1456:11 really [10] - 1269:12, 1278:13, 1281:11, 1281:13, 1285:15, 1294:5, 1318:7, 1346:7, 1378:18, 1409:16 realm [1] - 1271:15 reanalysis [1] - 1460:16 reanalyzed [2] - 1422:9, 1425:5 reason [15] - 1272:11, 1291:18, 1304:25, 1308:24, 1330:17, 1330:24, 1337:18, 1338:10, 1365:5, 1404:8, 1411:7, 1427:17, 1441:15, 1448:25 reasonable [3] - 1341:16, 1371:12, 1371:14</p>	<p>reasoning [1] - 1410:3 reasons [2] - 1281:22, 1404:3 REATH [1] - 1256:16 received [2] - 1365:22, 1427:18 receiving [1] - 1451:6 recent [3] - 1277:21, 1277:24, 1448:1 recently [2] - 1289:21, 1388:21 receptors [1] - 1388:21 recess [5] - 1316:14, 1353:12, 1414:17, 1440:7, 1440:8 recognition [1] - 1286:16 recognizable [1] - 1286:13 recognize [3] - 1291:11, 1303:16, 1385:21 recognized [6] - 1274:7, 1286:4, 1302:18, 1404:18, 1404:22, 1444:2 recommend [1] - 1426:16 recommendation [2] - 1322:1, 1322:4 record [4] - 1258:17, 1266:14, 1374:4, 1454:10 recorded [1] - 1415:21 RECROSS [1] - 1459:11 Recross [1] - 1468:7 RECROSS- EXAMINATION [1] - 1459:11 rectal [5] - 1401:21, 1402:6, 1403:9, 1441:25, 1442:10 red [2] - 1306:23, 1326:25 REDIRECT [2] - 1440:17, 1467:13 redirect [1] - 1338:17 Redirect [1] - 1468:7 redoing [1] - 1276:16 redox [1] - 1290:1 reduce [1] - 1314:4 reduced [1] - 1313:23 reduction [2] - 1289:9, 1289:18 refer [5] - 1383:6,</p>
<p>R</p> <p>radiation [1] - 1465:17 Radic [5] - 1383:4, 1383:17, 1384:20, 1385:6 radioactive [1] - 1450:16 radiology [2] - 1451:1, 1451:5 raised [1] - 1307:25 raises [8] - 1309:1, 1310:12, 1317:21, 1329:20, 1336:14, 1438:13, 1438:18, 1439:22 raising [1] - 1439:25 range [4] - 1274:4, 1341:1, 1341:12, 1408:3 ranges [2] - 1288:16, 1340:11 ranked [1] - 1272:23 rat [7] - 1300:15, 1387:13, 1388:22, 1388:25, 1395:25, 1397:6, 1453:6 Rat [1] - 1383:12 rate [2] - 1280:17, 1312:1 rather [4] - 1389:1, 1391:15, 1420:8, 1420:10 ratio [16] - 1275:16, 1277:8, 1311:16, 1406:13, 1406:16, 1406:19, 1407:5, 1407:9, 1407:13, 1411:20, 1422:22, 1429:4, 1429:13, 1430:8, 1453:25</p>			

1413:25, 1429:9, 1460:24, 1461:5 reference [17] - 1266:19, 1267:1, 1270:23, 1284:25, 1295:16, 1296:6, 1358:8, 1358:19, 1380:15, 1395:12, 1432:4, 1433:11, 1459:19, 1460:2, 1460:22, 1463:11, 1465:24 references [13] - 1298:19, 1299:25, 1303:25, 1375:1, 1395:6, 1395:13, 1398:5, 1400:17, 1417:18, 1418:4 1418:7, 1431:23, 1435:15 referencing [1] - 1385:22 referred [9] - 1285:9, 1286:6, 1286:17, 1290:7, 1371:20, 1377:11, 1388:1, 1390:13, 1392:6 referring [7] - 1300:13, 1323:6, 1335:7, 1356:16, 1400:17, 1423:5, 1451:23 refers [9] - 1266:7, 1266:16, 1324:15, 1335:7, 1355:4, 1384:24, 1386:13, 1462:14, 1463:9 reflected [2] - 1348:12, 1349:2 reflects [1] - 1348:18 refresh [2] - 1341:19, 1381:1 refuted [1] - 1344:18 regard [10] - 1271:20, 1276:25, 1283:4, 1297:10, 1300:23, 1304:15, 1361:13, 1439:21, 1441:1, 1441:8 regarding [47] - 1261:12, 1261:17, 1263:20, 1264:1, 1268:6, 1274:1, 1274:17, 1281:6, 1308:1, 1310:8, 1313:1, 1313:13, 1316:2, 1328:19, 1334:11, 1334:22, 1338:14,	1339:9, 1351:2, 1351:4, 1365:22, 1366:2, 1367:10, 1367:19, 1367:24, 1368:17, 1369:24, 1371:7, 1376:15, 1377:17, 1378:20, 1379:16, 1417:16, 1426:4, 1443:4, 1446:7, 1447:25, 1449:1, 1450:9, 1450:22, 1451:17, 1452:20, 1453:16, 1453:20, 1455:15, 1455:20, 1455:22 regardless [1] - 1372:24 region [3] - 1401:18, 1402:4, 1441:24 regular [4] - 1260:9, 1312:4, 1386:8, 1408:4 regularly [4] - 1283:11, 1310:19, 1401:25, 1442:15 regulates [1] - 1295:14 regulation [1] - 1288:22 regulators [1] - 1427:8 regulatory [6] - 1281:24, 1426:8, 1427:13, 1445:2, 1457:11, 1457:13 reiterate [2] - 1345:20, 1432:22 rejected [3] - 1332:13, 1432:7, 1432:11 rejection [1] - 1465:6 relate [2] - 1349:19, 1349:20 related [9] - 1320:2, 1331:6, 1332:10, 1337:22, 1354:13, 1354:17, 1357:1, 1396:4, 1410:15 relates [9] - 1279:7, 1293:4, 1294:12, 1339:9, 1362:16, 1368:14, 1390:15, 1394:21, 1425:17 relating [11] - 1293:6, 1324:8, 1324:9, 1347:17, 1348:22, 1349:7, 1354:22, 1394:21, 1396:19, 1420:18, 1466:2	relation [4] - 1277:1, 1295:4, 1449:5, 1456:12 relationship [18] - 1259:18, 1274:17, 1277:2, 1280:21, 1287:8, 1312:19, 1312:21, 1313:7, 1314:8, 1315:15, 1317:13, 1317:17, 1318:19, 1331:5, 1358:15, 1424:22, 1431:6, 1457:3 relative [16] - 1275:14, 1277:4, 1278:2, 1278:14, 1278:16, 1307:9, 1311:16, 1350:15, 1398:14, 1401:2, 1412:12, 1415:12, 1416:23, 1416:25, 1417:3, 1454:14 relatively [1] - 1298:13 release [3] - 1290:14, 1322:22, 1322:23 relegated [4] - 1306:11, 1306:17, 1306:22, 1307:3 relevance [1] - 1389:18 relevant [6] - 1274:25, 1288:14, 1289:23, 1368:15, 1446:1, 1465:17 reliability [1] - 1456:22 reliable [2] - 1363:1, 1458:10 reliance [5] - 1299:14, 1299:25, 1346:2, 1346:17, 1455:15 relied [10] - 1271:19, 1271:20, 1279:15, 1303:15, 1327:11, 1327:14, 1348:13, 1373:23, 1422:13, 1455:19 relies [1] - 1408:14 rely [10] - 1267:1, 1300:4, 1304:4, 1346:12, 1368:20, 1369:3, 1396:19, 1408:16, 1427:7, 1467:5 relying [3] - 1270:17, 1346:7, 1408:18 remaining [1] - 1366:14	remains [1] - 1364:16 remember [26] - 1320:13, 1338:2, 1340:14, 1340:16, 1340:22, 1354:21, 1354:25, 1382:16, 1385:13, 1388:4, 1406:7, 1421:3, 1421:16, 1424:15, 1433:7, 1433:8, 1438:15, 1438:21, 1443:6, 1453:18, 1463:4, 1464:3, 1464:8, 1464:10, 1466:22, 1467:7 reminded [1] - 1443:3 remove [1] - 1372:6 removed [1] - 1397:3 render [4] - 1317:18, 1361:20, 1450:8, 1452:3 rendered [1] - 1367:20 repair [1] - 1296:16 repeat [2] - 1330:22, 1402:25 repeats [1] - 1283:11 replicated [1] - 1346:16 report [134] - 1261:14, 1264:10, 1264:20, 1264:24, 1265:5, 1265:7, 1266:5, 1266:7, 1266:8, 1266:12, 1266:13, 1266:15, 1267:2, 1267:9, 1269:1, 1269:10, 1269:17, 1270:19, 1270:20, 1271:12, 1271:17, 1271:18, 1272:14, 1276:9, 1282:7, 1283:4, 1284:7, 1284:9, 1292:18, 1292:24, 1293:1, 1293:5, 1293:7, 1293:12, 1293:14, 1293:17, 1294:7, 1294:16, 1294:25, 1295:3, 1296:9, 1297:1, 1298:19, 1298:21, 1299:1, 1299:2, 1299:4, 1299:9, 1299:10, 1299:21, 1299:22, 1299:24, 1301:14, 1305:13, 1315:18, 1325:15, 1346:10, 1347:18, 1355:2,
---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

1355:23, 1356:12, 1359:23, 1360:2, 1367:18, 1367:21, 1368:24, 1369:15, 1369:21, 1370:9, 1373:21, 1373:22, 1374:3, 1374:6, 1374:16, 1374:18, 1374:23, 1375:2, 1375:6, 1375:8, 1379:23, 1380:16, 1383:7, 1390:8, 1391:24, 1392:2, 1392:13, 1395:3, 1395:7, 1395:12, 1395:14, 1395:17, 1397:17, 1397:19, 1397:21, 1398:22, 1403:3, 1403:14, 1405:1, 1405:18, 1406:6, 1411:25, 1414:9, 1414:10, 1416:19, 1417:9, 1417:11, 1417:22, 1417:25, 1418:5, 1418:14, 1418:16, 1425:12, 1427:14, 1430:24, 1432:5, 1433:9, 1434:12, 1435:12, 1438:1, 1438:3, 1441:9, 1446:19, 1448:24, 1449:5, 1449:14, 1449:18, 1452:14, 1456:1, 1457:5, 1457:13 reported [13] - 1277:25, 1315:20, 1348:17, 1372:19, 1372:20, 1373:5, 1384:2, 1387:18, 1388:22, 1392:14, 1394:4, 1423:21, 1430:2 REPORTER [1] - 1256:25 reporter [1] - 1414:13 reporting [4] - 1379:1, 1379:5, 1379:9, 1379:12 reports [6] - 1264:8, 1346:3, 1346:17, 1347:17, 1429:19, 1430:15 represent [4] - 1298:17, 1315:7, 1374:20, 1455:5	representation [2] - 1301:9, 1428:13 representative [1] - 1265:16 represents [1] - 1277:8 reproductive [22] - 1259:21, 1279:3, 1279:21, 1279:25, 1280:4, 1280:15, 1280:18, 1281:12, 1281:14, 1283:9, 1304:17, 1304:20, 1305:6, 1376:4, 1378:15, 1399:19, 1402:23, 1403:7, 1403:16, 1403:19, 1404:15, 1453:9 request [2] - 1260:13, 1436:21 require [3] - 1426:6, 1426:15, 1426:19 required [4] - 1292:23, 1336:7, 1338:10, 1338:22 requirement [1] - 1299:23 requires [2] - 1313:18, 1419:5 research [20] - 1278:17, 1281:16, 1290:21, 1291:3, 1291:14, 1311:2, 1312:2, 1313:5, 1313:6, 1313:11, 1332:8, 1342:15, 1346:23, 1347:17, 1351:9, 1369:18, 1369:23, 1392:13, 1410:17, 1426:14 Research [1] - 1259:1 researched [1] - 1352:1 researcher [1] - 1310:20 researchers [1] - 1315:19 residence [1] - 1305:1 Residency [1] - 1259:5 respect [11] - 1267:14, 1320:24, 1358:9, 1367:7, 1368:21, 1369:5, 1373:17, 1416:11, 1430:20, 1436:1, 1463:17 respiratory [7] - 1268:6, 1282:22, 1285:2,	1338:1, 1397:20, 1398:12, 1450:13 responded [1] - 1451:24 responding [1] - 1408:16 response [28] - 1261:11, 1261:12, 1293:21, 1312:13, 1312:15, 1312:19, 1312:20, 1318:19, 1331:5, 1333:1, 1337:5, 1345:10, 1367:6, 1368:21, 1369:4, 1369:7, 1373:11, 1378:14, 1379:9, 1379:12, 1382:17, 1384:21, 1388:17, 1394:12, 1409:10, 1424:9, 1454:13, 1454:14 responses [8] - 1260:6, 1274:15, 1291:25, 1379:1, 1379:5, 1387:18, 1387:19, 1437:9 result [16] - 1288:23, 1302:14, 1302:15, 1305:17, 1322:18, 1341:23, 1388:25, 1389:5, 1398:8, 1402:21, 1403:5, 1407:21, 1408:7, 1422:22, 1430:24 resulted [5] - 1281:8, 1298:16, 1298:17, 1299:8, 1413:1 resulting [1] - 1297:12 results [20] - 1295:13, 1295:15, 1313:19, 1313:23, 1314:21, 1331:25, 1333:10, 1334:8, 1334:16, 1346:1, 1347:14, 1348:13, 1348:16, 1349:2, 1422:25, 1423:5, 1429:10, 1455:21, 1461:22, 1461:23 results-oriented [1] - 1346:1 resumed [4] - 1317:4, 1354:6, 1415:5, 1440:15 retained [1] - 1317:12 retrograde [3] - 1280:8,	1280:9, 1282:9 retrospective [1] - 1312:9 Reuter [1] - 1303:22 review [23] - 1264:1, 1270:1, 1274:19, 1274:21, 1275:21, 1276:4, 1276:22, 1279:7, 1303:20, 1303:22, 1304:9, 1304:14, 1307:13, 1392:9, 1393:23, 1437:6, 1438:7, 1445:22, 1445:25, 1446:14, 1449:8, 1456:18, 1457:7 reviewed [17] - 1264:8, 1271:1, 1279:11, 1301:20, 1310:7, 1316:5, 1323:2, 1329:9, 1340:15, 1348:17, 1348:21, 1356:10, 1369:25, 1374:16, 1418:13, 1428:20, 1436:25 reviewer [1] - 1272:7 reviewing [3] - 1303:21, 1394:15, 1448:12 reviews [1] - 1393:1 right-hand [11] - 1301:16, 1325:12, 1357:10, 1382:18, 1386:17, 1386:21, 1388:8, 1391:1, 1393:24, 1397:8, 1422:15 right-side-up [1] - 1401:11 rise [10] - 1258:4, 1316:13, 1317:1, 1320:16, 1353:11, 1354:3, 1414:16, 1415:1, 1440:6, 1440:10 risen [2] - 1321:6, 1322:3 risk [56] - 1261:5, 1261:13, 1261:23, 1261:24, 1262:6, 1275:18, 1277:4, 1277:7, 1277:9, 1278:2, 1278:16, 1307:20, 1307:24, 1310:12, 1311:16, 1317:21, 1319:16, 1329:21,
-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

1330:11, 1331:8, 1331:21, 1331:25, 1333:6, 1333:18, 1335:1, 1335:13, 1336:10, 1336:14, 1360:6, 1360:14, 1393:2, 1403:19, 1404:4, 1406:10, 1406:24, 1407:21, 1408:7, 1408:19, 1409:19, 1410:4, 1412:11, 1413:14, 1415:12, 1415:22, 1416:25, 1417:3, 1422:21, 1425:1, 1425:6, 1435:2, 1441:3, 1441:4, 1453:25, 1454:2, 1462:9 risks [3] - 1275:14, 1278:14, 1416:23 robust [1] - 1407:15 rod [1] - 1450:23 rodent [3] - 1281:10, 1453:4, 1453:10 rodents [2] - 1281:11, 1398:15 rods [1] - 1450:15 Roman [3] - 1403:23, 1405:1, 1435:15 root [1] - 1439:20 ROSE [1] - 1256:19 roughly [1] - 1326:23 roulette [1] - 1420:25 route [10] - 1259:25, 1283:2, 1351:2, 1351:16, 1369:11, 1369:22, 1370:6, 1397:16, 1439:14, 1439:15 routine [1] - 1317:25 routinely [1] - 1345:18 row [3] - 1429:9, 1430:7, 1431:22 RPR [1] - 1256:24 rule [3] - 1267:22, 1398:2, 1435:8 ruled [4] - 1332:18, 1332:19, 1435:4, 1436:13 run [1] - 1344:9 rural [1] - 1340:4 Russoniello [2] - 1470:8, 1470:8	RUSSONIELLO [1] - 1256:24 S S/Vincent [1] - 1470:8 sac [7] - 1385:25, 1453:2, 1464:9, 1464:11, 1464:13, 1464:15, 1464:17 sacs [2] - 1464:5, 1464:20 Saed [1] - 1296:1 safe [9] - 1307:15, 1307:21, 1319:12, 1323:21, 1331:11, 1331:17, 1332:13, 1332:24, 1335:18 Safety [1] - 1261:7 safety [1] - 1323:8 SALES [1] - 1256:5 sample [3] - 1320:9, 1361:18, 1422:10 samples [1] - 1264:5 sampling [1] - 1322:18 satisfied [4] - 1270:13, 1312:6, 1312:11, 1313:17 saved [4] - 1407:18, 1408:13, 1408:22, 1409:10 saving [1] - 1407:21 saw [3] - 1291:22, 1365:21, 1453:6 scheme [2] - 1432:23, 1432:25 Schildkraut [1] - 1312:21 scholarly [2] - 1449:1, 1466:1 School [3] - 1258:22, 1321:24, 1411:6 schools [1] - 1340:24 science [5] - 1384:8, 1408:20, 1427:13, 1457:14 scientific [11] - 1313:12, 1332:3, 1345:15, 1359:10, 1384:9, 1384:18, 1419:4, 1426:3, 1426:24, 1457:17, 1467:3 scientist [2] - 1258:23, 1418:18 scientists [10] - 1276:5,	1319:15, 1344:14, 1344:15, 1344:25, 1346:16, 1464:9, 1464:19 screen [3] - 1286:23, 1395:5, 1461:19 screening [3] - 1425:8, 1445:19, 1446:17 search [1] - 1274:22 seated [2] - 1258:6, 1440:12 second [15] - 1289:14, 1321:12, 1324:1, 1373:9, 1380:5, 1380:15, 1392:25, 1394:24, 1409:13, 1413:11, 1417:8, 1429:9, 1431:2, 1431:11, 1431:23 secondary [5] - 1259:25, 1283:2, 1369:11, 1369:22, 1370:18 Section [2] - 1266:18, 1374:3 section [8] - 1357:25, 1358:16, 1374:5, 1374:10, 1374:14, 1374:21, 1454:22, 1462:6 SECTION [1] - 1470:3 see [48] - 1267:22, 1287:15, 1291:20, 1292:4, 1292:11, 1295:2, 1296:4, 1297:4, 1301:6, 1312:15, 1312:16, 1321:18, 1321:21, 1332:6, 1341:3, 1356:4, 1374:5, 1374:9, 1380:2, 1382:20, 1382:23, 1383:8, 1386:11, 1388:14, 1391:9, 1395:8, 1396:8, 1406:19, 1413:4, 1413:17, 1423:1, 1423:2, 1427:21, 1428:3, 1428:25, 1429:21, 1429:22, 1430:3, 1430:16, 1431:20, 1434:1, 1434:21, 1446:10, 1446:12, 1446:24, 1454:21, 1455:1,	1465:23 seeing [2] - 1300:24, 1409:17 seem [2] - 1298:13, 1308:15 senior [1] - 1431:12 sense [4] - 1313:13, 1347:4, 1351:18, 1417:9 sentence [23] - 1298:21, 1299:4, 1324:6, 1324:19, 1324:21, 1325:1, 1373:3, 1380:15, 1381:23, 1382:2, 1388:20, 1392:25, 1397:9, 1437:4, 1460:1, 1461:18, 1462:2, 1462:15, 1462:19, 1462:20, 1462:21, 1462:22, 1463:18 sentences [6] - 1293:7, 1299:11, 1299:22, 1299:24, 1389:14, 1403:23 separate [3] - 1349:10, 1360:7, 1414:2 separately [1] - 1266:3 sequestered [6] - 1260:2, 1283:6, 1283:7, 1284:22, 1285:22, 1451:9 sequesters [1] - 1404:3 series [5] - 1449:4, 1452:19, 1453:16, 1455:4, 1455:14 serous [10] - 1277:1, 1277:5, 1315:24, 1415:22, 1459:22, 1460:2, 1460:12, 1460:25, 1461:5, 1462:10 set [2] - 1420:3, 1420:4 sets [2] - 1283:15, 1349:10 setting [1] - 1276:19 several [3] - 1312:19, 1369:20, 1461:22 SEYFARRTH [1] - 1257:5 shape [2] - 1291:12, 1291:19 shape/size [1] - 1382:6 share [2] - 1259:13,
----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

1272:4 shared [1] - 1265:17 SHARKO [1] - 1256:16 SHAW [1] - 1257:5 sheet [1] - 1263:1 shelter [2] - 1322:1, 1322:4 shop [1] - 1450:3 Short [1] - 1440:8 shortly [1] - 1448:5 show [22] - 1281:23, 1289:16, 1290:22, 1291:16, 1307:21, 1312:20, 1314:7, 1323:24, 1344:16, 1345:1, 1360:16, 1375:24, 1395:6, 1397:24, 1398:2, 1404:12, 1406:9, 1408:18, 1453:20, 1453:24, 1454:12, 1454:14 showed [20] - 1277:2, 1277:3, 1278:12, 1280:5, 1280:9, 1280:13, 1280:20, 1289:1, 1289:5, 1289:7, 1289:25, 1290:13, 1322:17, 1346:11, 1386:4, 1414:2, 1416:18, 1453:17, 1456:17, 1464:2 Shower [22] - 1259:16, 1260:3, 1260:8, 1260:10, 1262:16, 1262:22, 1264:24, 1273:10, 1274:3, 1274:12, 1443:5 showing [12] - 1311:15, 1355:24, 1360:4, 1360:12, 1369:15, 1370:12, 1378:12, 1390:4, 1399:5, 1402:20, 1403:4, 1409:18 shown [11] - 1272:11, 1279:22, 1298:2, 1308:4, 1312:2, 1314:11, 1410:4, 1416:7, 1445:8, 1454:23, 1456:5 shows [13] - 1259:17, 1269:3, 1272:8,	1275:11, 1277:19, 1284:3, 1288:12, 1291:10, 1304:10, 1390:5, 1429:10, 1430:3, 1431:22 Shukla [7] - 1265:1, 1265:6, 1265:11, 1265:23, 1265:24, 1266:1, 1288:20 side [6] - 1303:4, 1325:14, 1401:11, 1422:16, 1453:3, 1456:15 sights [1] - 1383:19 significant [28] - 1259:16, 1263:24, 1275:15, 1277:4, 1277:10, 1278:3, 1278:7, 1278:8, 1278:15, 1282:25, 1311:17, 1349:13, 1349:19, 1354:24, 1355:18, 1375:15, 1407:2, 1409:18, 1413:2, 1413:22, 1415:12, 1416:23, 1417:6, 1425:6, 1437:24, 1453:25, 1456:19, 1462:8 significantly [3] - 1417:19, 1423:20, 1449:17 similar [16] - 1261:5, 1281:1, 1281:24, 1288:17, 1288:18, 1294:17, 1304:18, 1314:1, 1314:6, 1314:10, 1314:16, 1422:22, 1441:15, 1447:2, 1447:5, 1448:19 similarity [1] - 1314:8 simple [1] - 1306:2 simply [4] - 1294:15, 1302:6, 1338:18, 1410:3 single [4] - 1290:7, 1409:1, 1438:1, 1441:4 sit [3] - 1327:17, 1365:24, 1366:5 site [1] - 1451:12 sites [1] - 1451:7 sitting [1] - 1401:12 situation [1] - 1310:23 situations [1] - 1262:20	six [3] - 1289:23, 1398:10, 1418:3 size [6] - 1281:1, 1281:3, 1291:12, 1291:19, 1422:10, 1456:21 sizes [1] - 1456:23 SKADDEN [1] - 1256:18 skin [1] - 1380:7 skip [1] - 1388:20 SLATE [1] - 1256:18 slide [27] - 1262:23, 1264:18, 1268:15, 1272:9, 1272:11, 1279:22, 1279:23, 1286:23, 1288:5, 1288:12, 1292:4, 1293:24, 1295:4, 1295:8, 1297:22, 1298:2, 1298:18, 1299:12, 1306:2, 1310:15, 1388:1, 1431:18, 1436:18, 1455:13, 1456:6, 1459:14 slides [5] - 1260:13, 1264:13, 1296:24, 1376:12, 1453:13 slightly [2] - 1314:13, 1462:13 slippery [1] - 1263:1 small [13] - 1282:22, 1285:8, 1287:9, 1318:15, 1318:20, 1347:3, 1363:9, 1363:11, 1413:14, 1413:22, 1414:1, 1443:11, 1462:7 smell [1] - 1263:11 smoking [2] - 1458:15, 1458:16 smoothness [1] - 1382:6 snapshot [1] - 1447:15 SNPs [1] - 1290:8 sole [1] - 1397:16 solutions [1] - 1361:10 sometime [1] - 1303:4 sometimes [1] - 1407:14 somewhat [2] - 1314:14, 1447:5 somewhere [2] - 1286:22, 1309:4 sore [1] - 1283:14 sorry [3] - 1291:9,
-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

specificity [2] - 1311:22, 1312:5	States [7] - 1406:25, 1408:5, 1425:24, 1426:2, 1426:6, 1427:3, 1427:10	stimulate [1] - 1293:21	1400:3
specifying [1] - 1356:20	STATES [2] - 1256:1, 1256:7	stimulation [1] - 1296:19	studies [234] - 1259:17, 1261:18, 1274:16,
specimens [2] - 1263:16, 1280:21	states [5] - 1264:23, 1298:5, 1299:21, 1301:1, 1360:24	stoke [1] - 1321:20	1274:23, 1275:2,
speculating [3] - 1347:9, 1362:6, 1362:10	stating [2] - 1320:20, 1433:24	stole [1] - 1261:8	1275:11, 1275:12,
speculation [3] - 1371:7, 1438:23, 1466:24	statistical [5] - 1325:16, 1409:18, 1410:8, 1420:14, 1422:20	stop [2] - 1280:22, 1426:13	1275:13, 1275:19,
spell [1] - 1289:12	statistically [18] -	story [1] - 1278:13	1275:20, 1275:22,
sperm [4] - 1280:14, 1280:16, 1281:4, 1401:15	1275:15, 1277:10, 1278:2, 1278:7, 1278:8, 1278:15, 1311:17, 1349:12, 1349:19, 1354:23, 1413:2, 1413:22, 1416:23, 1417:6, 1425:6, 1453:24, 1456:19, 1462:8	STREET [1] - 1256:7	1276:5, 1276:13,
spinning [1] - 1420:24	statistician [4] - 1410:6, 1410:11, 1410:14, 1410:22	strength [8] - 1311:3, 1314:20, 1394:17, 1405:16, 1405:19, 1405:23, 1409:11, 1411:19	1276:25, 1277:3,
stage [1] - 1286:6	statistics [1] - 1410:15	strengthening [1] - 1456:22	1277:13, 1277:14,
stages [1] - 1286:14	stay [1] - 1452:7	strengths [1] - 1393:22	1278:6, 1278:9,
stainless [2] - 1450:3, 1450:4	stayed [1] - 1451:8	stress [9] - 1289:6, 1289:17, 1377:25, 1378:1, 1378:6, 1378:8, 1402:21, 1403:5, 1437:8	1279:18, 1280:7,
stalls [1] - 1404:3	steel [2] - 1450:3, 1450:4	stretch [1] - 1292:14	1280:8, 1281:5, 1281:9,
stand [1] - 1278:11	Steering [1] - 1256:14	strike [8] - 1324:19, 1339:13, 1344:13, 1347:1, 1347:20, 1419:25, 1420:8, 1449:12	1287:5, 1287:18,
standard [7] - 1295:24, 1321:25, 1322:4, 1325:17, 1326:11, 1328:7, 1337:14	STENOGRAPHIC [1] - 1470:5	stretching [1] - 1297:19, 1297:23, 1298:2, 1301:19, 1303:9, 1303:13, 1303:14, 1303:16,	1287:19, 1287:20,
standards [2] - 1295:23, 1345:14	step [18] - 1261:5, 1262:4, 1262:5, 1274:13, 1277:22, 1286:5, 1286:11, 1287:3, 1315:10, 1315:11, 1316:12, 1324:8, 1324:9, 1325:3, 1376:11, 1417:8, 1466:1	strong [23] - 1287:7, 1288:4, 1303:6, 1303:17, 1311:7, 1314:8, 1334:11, 1406:3, 1406:6, 1406:22, 1407:1, 1407:9, 1407:15, 1411:21, 1412:17, 1412:22, 1413:8, 1414:7, 1426:12, 1433:5, 1433:16, 1434:13, 1434:20	1287:22, 1288:6,
standing [1] - 1401:11	step-by-step [1] - 1261:5	stronger [3] - 1306:15, 1406:21, 1427:17	1288:10, 1288:13,
standpoint [2] - 1321:1, 1322:15	stepping [1] - 1268:15	strongly [2] - 1291:5, 1355:10	1288:14, 1288:16,
stands [1] - 1276:10	steps [4] - 1287:10, 1287:11, 1287:14, 1363:17	structurally [1] - 1314:10	1290:9, 1290:12,
starch [1] - 1298:8	steroid [4] - 1388:21, 1389:2, 1389:7, 1389:10	structure [3] - 1292:6, 1314:8, 1370:8	1290:17, 1290:20,
starches [1] - 1298:13	still [7] - 1281:21, 1306:15, 1309:13, 1344:2, 1351:11, 1351:17, 1355:20	structure-function [1] - 1314:8	1290:22, 1291:22,
start [3] - 1322:20, 1378:9, 1459:13		structures [2] - 1279:6, 1302:22	1297:18, 1297:19,
started [1] - 1276:13		students [1] - 1310:21	1297:23, 1297:25,
starting [3] - 1277:20, 1291:3, 1442:5		studied [6] - 1280:2, 1280:11, 1280:23, 1288:16, 1291:15,	1298:2, 1301:19,
state [12] - 1258:17, 1305:13, 1341:16, 1361:3, 1361:16, 1362:2, 1362:7, 1362:13, 1362:14, 1375:6, 1396:3, 1427:12			1303:9, 1303:13,
STATE [1] - 1256:7			1303:14, 1303:16,
State [2] - 1259:9, 1451:10			1308:4, 1308:9,
State's [1] - 1465:16			1309:12, 1311:4,
statement [9] - 1305:15, 1321:8, 1331:3, 1340:16, 1344:18, 1359:2, 1382:12, 1445:5, 1463:22			1311:5, 1311:12,
statements [1] - 1366:2			1311:15, 1311:18,
			1311:20, 1312:8,
			1312:10, 1312:15,
			1312:17, 1312:18,
			1312:22, 1312:24,
			1315:21, 1315:24,
			1324:8, 1324:9, 1325:4,
			1326:9, 1327:15,
			1329:8, 1330:19,
			1331:1, 1331:4,
			1334:19, 1334:22,
			1344:9, 1348:13,
			1348:16, 1348:22,
			1349:3, 1349:6, 1349:7,
			1349:10, 1349:12,
			1349:16, 1349:24,
			1350:3, 1350:5,
			1350:10, 1352:14,
			1354:13, 1354:17,
			1354:18, 1354:23,
			1355:6, 1355:10,
			1355:14, 1355:16,
			1355:18, 1355:21,
			1355:24, 1356:4,

1356:8, 1356:10, 1359:5, 1360:4, 1360:7, 1360:12, 1360:16, 1369:14, 1371:19, 1372:10, 1373:23, 1375:11, 1378:16, 1378:17, 1379:1, 1379:4, 1379:11, 1379:14, 1379:17, 1379:18, 1379:23, 1385:12, 1389:16, 1389:20, 1389:24, 1392:5, 1393:23, 1394:20, 1394:21, 1396:7, 1396:10, 1396:18, 1399:5, 1399:9, 1402:20, 1403:4, 1404:25, 1405:8, 1405:24, 1406:9, 1407:2, 1408:18, 1409:18, 1410:5, 1412:2, 1414:10, 1415:10, 1415:11, 1415:17, 1416:6, 1416:7, 1416:18, 1416:22, 1417:22, 1418:3, 1418:10, 1418:13, 1418:19, 1418:20, 1418:22, 1418:24, 1419:9, 1419:15, 1420:18, 1420:24, 1421:1, 1421:8, 1421:20, 1421:24, 1421:25, 1422:8, 1422:12, 1422:17, 1422:21, 1422:23, 1423:7, 1423:10, 1423:25, 1424:2, 1424:4, 1424:6, 1424:7, 1424:13, 1424:21, 1425:5, 1427:24, 1430:20, 1435:1, 1435:20, 1437:14, 1446:1, 1446:6, 1446:11, 1446:23, 1447:9, 1447:11, 1447:14, 1447:15, 1447:18, 1449:6, 1449:8, 1451:5, 1453:15, 1455:4, 1456:22, 1459:20, 1460:11, 1460:16, 1461:4, 1461:8,	1461:24, 1462:3, 1462:11, 1462:15, 1462:16, 1462:17, 1463:4, 1463:18, 1463:19, 1465:4, 1466:2, 1467:5 study [166] - 1265:11, 1275:1, 1275:23, 1276:22, 1277:18, 1278:4, 1278:11, 1280:19, 1280:25, 1281:17, 1281:23, 1288:20, 1289:1, 1289:5, 1289:14, 1289:21, 1289:24, 1290:13, 1298:5, 1298:14, 1298:20, 1298:21, 1298:22, 1298:24, 1299:6, 1299:8, 1299:14, 1299:16, 1299:17, 1300:1, 1300:5, 1300:12, 1300:24, 1301:10, 1308:21, 1312:21, 1323:8, 1324:2, 1347:12, 1347:25, 1354:22, 1360:8, 1362:12, 1370:12, 1371:20, 1371:23, 1372:2, 1372:19, 1373:4, 1373:9, 1373:16, 1378:12, 1379:8, 1380:18, 1381:6, 1381:12, 1381:14, 1382:15, 1383:2, 1383:4, 1383:5, 1383:11, 1383:21, 1385:6, 1385:10, 1385:13, 1385:16, 1385:18, 1385:21, 1385:24, 1387:9, 1387:10, 1387:14, 1388:1, 1388:4, 1389:21, 1389:22, 1390:3, 1390:5, 1390:9, 1390:13, 1390:19, 1390:24, 1391:23, 1391:24, 1392:2, 1392:13, 1395:8, 1395:11, 1395:13, 1396:16, 1396:18, 1396:22, 1397:1,	1397:2, 1397:15, 1397:17, 1398:21, 1406:2, 1406:19, 1412:20, 1415:22, 1415:24, 1416:1, 1416:12, 1416:14, 1419:11, 1419:16, 1419:18, 1419:19, 1419:22, 1420:2, 1420:4, 1420:7, 1420:8, 1420:9, 1420:10, 1420:11, 1420:12, 1420:13, 1420:14, 1421:16, 1421:22, 1422:5, 1422:12, 1422:24, 1424:18, 1424:19, 1428:3, 1428:24, 1429:25, 1430:5, 1436:17, 1436:24, 1438:1, 1438:2, 1438:4, 1441:2, 1441:7, 1441:10, 1452:21, 1454:4, 1459:14, 1460:5, 1460:6, 1460:8, 1460:13, 1460:17, 1460:18, 1461:9, 1461:10, 1461:13, 1461:14, 1461:16, 1462:22, 1463:9, 1464:2, 1464:19, 1464:25 Study [2] - 1415:16, 1416:11 study's [2] - 1429:20, 1430:16 stuff [1] - 1292:18 style [1] - 1426:5 subcutaneous [1] - 1383:18 subject [10] - 1262:8, 1294:2, 1297:2, 1297:6, 1303:21, 1351:9, 1376:11, 1400:11, 1400:13, 1450:20 subjected [1] - 1465:1 subjects [4] - 1420:5, 1420:21, 1421:1, 1421:10 subsequent [1] - 1317:15 subset [1] - 1375:4 substance [14] -	1279:20, 1289:10, 1318:14, 1318:16, 1324:16, 1326:23, 1332:3, 1332:14, 1333:7, 1356:23, 1356:25, 1357:20, 1359:11 substances [9] - 1273:22, 1274:8, 1298:9, 1323:10, 1323:16, 1356:19, 1368:10, 1400:18, 1404:5 subtypes [1] - 1416:9 suffered [1] - 1422:8 suffice [1] - 1268:14 sufficient [10] - 1337:25, 1357:12, 1358:2, 1359:10, 1370:17, 1420:20, 1421:9, 1421:18, 1423:25, 1434:16 suggest [4] - 1301:24, 1322:2, 1398:7, 1437:14 suggested [1] - 1325:8 suggesting [1] - 1462:21 suggestive [3] - 1315:25, 1459:22, 1460:23 suggests [4] - 1313:24, 1325:15, 1413:13, 1455:5 sum [2] - 1301:19, 1335:20 summarize [1] - 1387:9 summarized [1] - 1389:13 summarizing [1] - 1285:20 summary [4] - 1259:14, 1300:18, 1358:16, 1455:12 supplied [1] - 1296:24 supplier [1] - 1264:12 suppliers [1] - 1343:1 suppliers' [1] - 1344:15 support [12] - 1297:25, 1301:21, 1303:10, 1303:25, 1379:23, 1390:20, 1405:1, 1409:14, 1412:21, 1414:5, 1461:24, 1466:25 supported [4] - 1393:16,
-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

1415:23, 1416:12, 1444:25 supporting [2] - 1316:6, 1359:3 supportive [1] - 1394:2 supports [6] - 1282:10, 1383:5, 1390:19, 1406:2, 1411:21, 1444:17 supposed [1] - 1332:4 suppressed [1] - 1384:21 suppression [1] - 1384:24 surely [1] - 1330:23 surface [9] - 1283:10, 1301:4, 1361:9, 1386:5, 1386:25, 1388:11, 1388:22, 1388:24, 1389:19 surgery [2] - 1302:16, 1303:5 surgical [3] - 1302:11, 1303:3, 1314:2 surgically [1] - 1385:24 surrogates [4] - 1328:15, 1328:17, 1328:21, 1458:10 surrounding [2] - 1320:16, 1376:9 surrounds [1] - 1453:2 survivability [1] - 1290:6 survive [1] - 1286:9 SUSAN [1] - 1256:16 suspect [1] - 1442:13 suspicion [7] - 1287:7, 1309:2, 1426:12, 1438:13, 1438:18, 1439:23, 1439:25 sustain [1] - 1332:21 swallowed [1] - 1285:11 sworn [1] - 1258:11 synonym [1] - 1272:18 synthesis [1] - 1437:25 system [32] - 1279:3, 1279:21, 1280:1, 1280:4, 1280:15, 1280:18, 1281:12, 1281:14, 1282:22, 1283:9, 1285:2, 1285:3, 1285:10, 1285:12, 1285:14, 1285:17, 1291:25, 1292:1,	1305:6, 1306:3, 1384:25, 1391:14, 1403:16, 1404:1, 1404:10, 1404:15, 1404:17, 1404:22, 1405:3, 1437:8, 1450:2, 1450:13 systematic [2] - 1274:21, 1445:22 systematically [1] - 1262:13 systems [1] - 1397:20	1272:12, 1272:13, 1272:15, 1272:16, 1272:20, 1272:22, 1273:2, 1273:4, 1274:18, 1280:20, 1280:21, 1282:4, 1282:11, 1283:3, 1283:12, 1283:17, 1284:3, 1288:15, 1288:21, 1288:23, 1289:23, 1291:20, 1293:6, 1293:10, 1293:11, 1293:17, 1296:5, 1298:12, 1298:15, 1300:16, 1302:10, 1302:12, 1302:15, 1302:18, 1302:20, 1303:3, 1303:5, 1303:6, 1303:8, 1303:17, 1304:13, 1305:3, 1305:7, 1306:9, 1306:13, 1311:7, 1311:8, 1313:7, 1314:10, 1315:24, 1328:11, 1328:24, 1329:1, 1330:20, 1331:2, 1335:21, 1335:22, 1336:1, 1336:4, 1341:24, 1344:7, 1347:15, 1348:16, 1348:19, 1349:8, 1351:7, 1351:24, 1358:3, 1358:4, 1358:9, 1358:23, 1359:4, 1359:20, 1360:6, 1360:10, 1360:13, 1361:4, 1361:7, 1361:17, 1361:19, 1362:3, 1362:8, 1362:17, 1363:10, 1363:13, 1363:18, 1364:4, 1364:7, 1364:8, 1364:14, 1364:17, 1364:20, 1365:2, 1367:3, 1367:12, 1367:16, 1369:15, 1369:19, 1369:22, 1371:5, 1371:8, 1371:15, 1371:23, 1371:24, 1371:25, 1372:19, 1372:23, 1372:24, 1373:11, 1373:18, 1376:7,	1378:17, 1379:1, 1379:5, 1379:15, 1379:18, 1380:6, 1380:15, 1380:23, 1381:8, 1382:25, 1383:6, 1383:13, 1383:18, 1384:2, 1386:3, 1387:15, 1388:5, 1390:4, 1390:10, 1390:17, 1391:3, 1391:13, 1394:1, 1394:3, 1394:18, 1394:22, 1395:22, 1395:25, 1396:6, 1397:6, 1397:10, 1397:16, 1397:18, 1397:25, 1398:8, 1398:9, 1398:10, 1399:5, 1399:17, 1399:22, 1399:23, 1401:14, 1401:20, 1401:23, 1402:5, 1402:22, 1403:6, 1404:1, 1405:12, 1406:3, 1408:14, 1411:22, 1413:3, 1416:8, 1420:19, 1422:19, 1424:25, 1426:20, 1427:25, 1431:23, 1432:7, 1432:11, 1432:20, 1433:3, 1434:4, 1434:8, 1434:25, 1435:7, 1437:7, 1437:10, 1437:15, 1437:22, 1438:5, 1441:8, 1441:14, 1441:25, 1444:14, 1447:3, 1447:25, 1448:9, 1448:13, 1448:14, 1448:16, 1448:19, 1452:9, 1452:20, 1453:21, 1455:3, 1455:5, 1455:16, 1455:23, 1457:22, 1458:25, 1459:2, 1459:21, 1462:9, 1463:20 talc-based [1] - 1434:25 talc-induced [1] - 1289:23 Talcum [2] - 1380:2,
-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

1433:10 talcum [153] - 1259:19, 1259:20, 1259:25, 1263:17, 1277:15, 1278:20, 1278:23, 1279:16, 1281:2, 1281:25, 1282:15, 1282:19, 1282:20, 1283:5, 1283:7, 1284:22, 1285:21, 1286:19, 1286:21, 1287:23, 1287:25, 1288:3, 1289:25, 1290:10, 1290:18, 1290:22, 1291:1, 1292:22, 1293:19, 1296:11, 1297:16, 1298:1, 1298:7, 1301:21, 1301:25, 1302:3, 1304:21, 1305:11, 1306:9, 1307:2, 1310:11, 1312:3, 1312:9, 1313:8, 1313:15, 1314:15, 1315:7, 1315:8, 1315:15, 1316:2, 1316:7, 1317:14, 1317:20, 1318:4, 1326:7, 1327:18, 1327:20, 1328:3, 1329:13, 1329:18, 1329:20, 1330:6, 1330:10, 1331:6, 1331:16, 1331:20, 1332:25, 1333:6, 1333:22, 1335:2, 1335:8, 1335:24, 1336:7, 1336:12, 1336:23, 1337:3, 1338:25, 1342:4, 1342:7, 1342:13, 1342:21, 1343:6, 1343:14, 1343:20, 1343:23, 1343:24, 1344:3, 1346:22, 1346:24, 1347:2, 1347:4, 1347:7, 1348:6, 1348:12, 1348:22, 1349:1, 1349:25, 1352:16, 1359:19, 1362:23, 1363:5, 1365:8, 1365:14, 1365:20, 1365:23,	1366:12, 1366:21, 1367:23, 1368:8, 1368:18, 1369:11, 1370:5, 1371:6, 1376:3, 1378:13, 1384:21, 1385:25, 1396:20, 1396:23, 1400:14, 1400:15, 1400:18, 1401:17, 1401:19, 1402:3, 1403:20, 1406:10, 1407:20, 1408:4, 1408:10, 1409:22, 1414:1, 1414:6, 1415:13, 1441:23, 1442:9, 1443:9, 1443:15, 1443:20, 1443:24, 1444:8, 1444:15, 1446:2, 1446:7, 1452:2, 1453:25, 1457:4, 1457:22, 1458:5, 1464:20, 1465:2, 1467:18 talks [5] - 1266:24, 1293:16, 1393:22, 1394:17, 1396:22 tantamount [1] - 1399:10 target [1] - 1296:11 teach [2] - 1310:21, 1410:17 technetium [1] - 1280:3 technetium-labeled [1] - 1280:3 temporality [2] - 1312:7, 1312:11 ten [1] - 1454:22 tend [1] - 1424:7 tenets [1] - 1318:10 tenfold [1] - 1340:8 term [9] - 1272:17, 1296:17, 1388:25, 1389:6, 1389:9, 1404:18, 1404:23, 1439:22, 1451:8 terminology [2] - 1406:21, 1407:11 terms [23] - 1290:17, 1293:16, 1296:23, 1318:4, 1318:8, 1333:11, 1351:15, 1351:17, 1363:1, 1366:13, 1367:2, 1398:22, 1401:4,	1407:11, 1420:25, 1438:5, 1441:1, 1445:7, 1447:22, 1452:1, 1453:9, 1457:23 Terry [4] - 1278:3, 1412:3, 1412:5, 1453:23 TERSIGNI [1] - 1256:17 test [4] - 1289:25, 1312:18, 1361:6, 1455:20 tested [1] - 1313:19 testified [21] - 1258:11, 1266:20, 1266:22, 1266:23, 1270:24, 1271:14, 1283:22, 1294:25, 1295:20, 1328:20, 1329:15, 1329:20, 1334:17, 1342:3, 1342:7, 1363:8, 1377:2, 1407:20, 1438:10, 1438:12, 1455:19 testify [3] - 1332:18, 1371:12, 1371:14 testifying [6] - 1268:3, 1271:12, 1271:16, 1293:9, 1331:19, 1339:19 testimony [32] - 1276:1, 1284:1, 1299:5, 1299:7, 1309:6, 1327:1, 1327:3, 1327:12, 1334:13, 1335:3, 1338:19, 1338:20, 1343:9, 1345:5, 1345:9, 1370:11, 1400:16, 1402:11, 1436:12, 1436:15, 1438:15, 1441:17, 1442:18, 1442:19, 1443:3, 1446:15, 1449:21, 1465:6, 1465:14, 1465:15, 1466:11, 1466:18 testing [4] - 1269:19, 1389:5, 1396:14, 1455:15 tests [7] - 1295:23, 1295:24, 1344:16, 1345:1, 1345:25, 1404:12, 1404:16 Texas [9] - 1258:22, 1259:2, 1320:7,	1322:13, 1337:14, 1411:6, 1450:1, 1465:7, 1467:16 texas [1] - 1337:15 textbooks [3] - 1400:11, 1400:12, 1400:23 THE [131] - 1256:1, 1256:9, 1258:4, 1258:5, 1259:11, 1259:12, 1260:15, 1265:6, 1265:13, 1265:24, 1266:2, 1266:11, 1267:6, 1267:20, 1267:25, 1268:4, 1268:12, 1268:25, 1269:6, 1269:9, 1269:13, 1269:14, 1269:15, 1269:16, 1269:18, 1269:24, 1270:11, 1271:3, 1271:9, 1271:24, 1276:3, 1276:12, 1276:19, 1277:22, 1283:19, 1283:21, 1283:22, 1283:24, 1283:25, 1284:2, 1284:6, 1284:8, 1294:1, 1294:9, 1294:19, 1294:22, 1295:18, 1296:22, 1298:25, 1299:7, 1299:15, 1300:3, 1301:13, 1308:19, 1309:1, 1309:5, 1309:9, 1309:10, 1309:11, 1309:17, 1315:1, 1315:4, 1316:11, 1316:13, 1317:1, 1317:2, 1327:5, 1329:25, 1332:21, 1333:14, 1336:17, 1344:21, 1346:6, 1346:10, 1347:22, 1347:25, 1350:17, 1351:20, 1352:9, 1352:11, 1352:21, 1353:9, 1353:11, 1354:3, 1354:4, 1361:23, 1364:10, 1366:17, 1368:4, 1369:1, 1370:10, 1370:14, 1370:16, 1370:19, 1370:24,
--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

1370:25, 1371:2, 1371:4, 1371:10, 1371:14, 1371:17, 1376:25, 1377:20, 1378:22, 1381:3, 1410:9, 1410:19, 1411:13, 1414:11, 1414:13, 1414:16, 1415:1, 1415:2, 1416:4, 1428:13, 1440:5, 1440:6, 1440:10, 1440:11, 1442:24, 1445:16, 1454:8, 1456:9, 1459:6, 1459:9, 1462:20, 1466:16, 1467:11, 1467:21, 1470:3, 1470:5 themselves [4] - 1278:11, 1291:12, 1389:13, 1464:18 theoretically [1] - 1318:24 theory [8] - 1313:25, 1369:9, 1376:15, 1378:10, 1379:18, 1392:15, 1405:1, 1466:25 therapeutically [1] - 1302:18 thereby [1] - 1455:7 therefore [3] - 1306:22, 1345:19, 1388:23 thinking [1] - 1269:7 thinks [1] - 1298:25 third [6] - 1300:23, 1357:25, 1395:2, 1403:1, 1429:2, 1431:4 THOMAS [1] - 1257:6 THOMPSON [1] - 1256:12 thoriated [3] - 1450:15, 1450:23, 1467:4 thorium [9] - 1337:25, 1338:11, 1450:16, 1450:17, 1450:19, 1450:25, 1451:3, 1451:7, 1451:11 Thorotrast [2] - 1451:1, 1467:6 thorough [1] - 1446:5 three [6] - 1277:21, 1277:24, 1309:22, 1320:10, 1416:17,	1418:24 threshold [15] - 1319:17, 1329:12, 1330:13, 1330:18, 1330:24, 1331:7, 1331:9, 1331:10, 1331:23, 1332:14, 1333:6, 1335:1, 1336:3, 1338:9, 1338:21 thresholds [4] - 1334:11, 1334:22, 1335:13, 1335:18 throat [3] - 1450:7, 1451:11, 1467:4 throughout [1] - 1308:18 throwing [1] - 1371:10 Thursday [1] - 1421:15 TIG [1] - 1450:4 time-wise [1] - 1456:9 tissue [23] - 1284:4, 1305:2, 1308:10, 1365:1, 1373:13, 1376:8, 1383:21, 1394:4, 1396:10, 1403:16, 1403:17, 1403:18, 1404:4, 1438:13, 1438:15, 1438:20, 1439:21, 1439:24, 1449:2 tissues [19] - 1260:1, 1282:24, 1296:11, 1308:12, 1309:3, 1309:5, 1309:7, 1309:14, 1376:9, 1380:7, 1380:11, 1391:6, 1402:7, 1403:11, 1442:1, 1442:11, 1442:12, 1443:12, 1451:4 TITLE [1] - 1470:3 TO [2] - 1470:3, 1470:4 today [22] - 1284:9, 1327:17, 1362:1, 1365:24, 1376:13, 1384:9, 1385:12, 1385:22, 1387:24, 1389:20, 1392:6, 1418:6, 1438:10, 1442:16, 1443:2, 1446:15, 1446:23, 1451:9, 1459:15, 1463:15, 1464:2, 1466:8 together [2] - 1287:14,	1378:18 tomorrow [1] - 1279:14 took [4] - 1294:9, 1394:6, 1397:2, 1397:3 top [7] - 1292:3, 1306:6, 1324:12, 1357:10, 1383:7, 1413:19, 1463:10 topic [10] - 1264:21, 1266:9, 1274:24, 1304:14, 1369:8, 1379:20, 1436:16, 1438:9, 1457:1, 1463:1 topics [1] - 1405:5 total [7] - 1373:25, 1374:14, 1422:18, 1423:21, 1437:14, 1438:23, 1454:15 totality [2] - 1261:21, 1310:8 toward [3] - 1322:21, 1323:5, 1424:7 toxic [1] - 1293:20 toxicity [5] - 1293:12, 1319:6, 1360:20, 1361:13, 1437:8 toxicological [2] - 1332:25, 1438:25 toxicologist [5] - 1319:18, 1321:25, 1323:12, 1337:10, 1339:18 toxicologists [5] - 1318:18, 1323:8, 1323:15, 1323:21, 1332:2 toxicology [3] - 1258:23, 1259:12, 1318:10 toxin [1] - 1441:4 toxins [3] - 1322:8, 1441:3, 1441:5 TP53 [1] - 1296:16 trace [3] - 1274:6, 1306:21, 1365:1 track [2] - 1338:1, 1403:19 tract [9] - 1259:21, 1282:16, 1304:17, 1304:20, 1376:4, 1378:15, 1399:19, 1402:23, 1403:7 training [3] - 1307:14, 1339:8, 1376:23	transcript [1] - 1442:22 TRANSCRIPT [1] - 1470:4 TRANSCRIPTION [1] - 1470:5 transcription [1] - 1295:14 transferred [1] - 1376:3 transformation [2] - 1289:2, 1298:16 transition [5] - 1278:18, 1282:16, 1297:19, 1307:11, 1457:1 transitioning [1] - 1303:8 translation [1] - 1406:23 transport [6] - 1279:24, 1280:1, 1281:22, 1282:9, 1282:14, 1404:1 traveled [2] - 1280:14, 1280:16 treat [2] - 1284:19, 1376:18 treated [4] - 1296:4, 1376:21, 1377:3, 1421:17 trends [2] - 1416:18, 1416:22 TRENTON [1] - 1256:7 trial [2] - 1276:2, 1449:22 tried [1] - 1458:13 trouble [1] - 1374:6 True [6] - 1333:10, 1337:4, 1345:16, 1351:10, 1352:17, 1360:6 true [79] - 1266:6, 1320:17, 1328:8, 1329:4, 1329:5, 1333:5, 1333:8, 1334:17, 1337:20, 1338:12, 1339:5, 1339:11, 1340:12, 1342:16, 1344:8, 1346:3, 1346:20, 1348:15, 1349:3, 1349:10, 1349:15, 1349:22, 1354:25, 1355:20, 1359:22, 1359:25, 1361:4, 1362:9, 1362:18, 1363:14, 1364:2, 1364:5, 1365:2, 1365:3, 1368:16,
-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

<p>1373:19, 1373:25, 1374:14, 1375:4, 1375:9, 1375:13, 1375:14, 1376:19, 1376:20, 1378:6, 1382:11, 1383:25, 1384:5, 1385:4, 1385:10, 1387:20, 1389:12, 1389:13, 1395:14, 1397:18, 1399:19, 1399:23, 1401:3, 1401:15, 1402:24, 1406:17, 1411:25, 1412:3, 1417:1, 1417:6, 1417:10, 1417:25, 1420:21, 1424:9, 1426:22, 1427:7, 1432:8, 1435:9, 1443:23, 1460:14, 1462:14, 1463:22, 1465:9</p> <p>truth [1] - 1363:13</p> <p>try [1] - 1292:2</p> <p>trying [7] - 1268:16, 1274:22, 1281:16, 1308:25, 1427:5, 1447:23, 1466:17</p> <p>tubal [1] - 1313:22</p> <p>tubes [7] - 1278:25, 1279:17, 1280:13, 1379:12, 1379:15, 1399:8, 1444:12</p> <p>tumor [3] - 1286:13, 1286:17, 1451:13</p> <p>tungsten [3] - 1450:5, 1450:15, 1450:23</p> <p>turn [20] - 1268:19, 1273:8, 1288:5, 1293:15, 1305:10, 1321:23, 1379:19, 1381:21, 1386:16, 1395:20, 1413:10, 1429:7, 1436:18, 1440:19, 1441:19, 1445:18, 1446:9, 1454:4, 1454:9, 1454:17</p> <p>turning [1] - 1456:13</p> <p>two [20] - 1276:5, 1286:5, 1293:7, 1302:22, 1306:2, 1321:10, 1349:10, 1351:14, 1376:1,</p>	<p>1376:11, 1395:25, 1396:2, 1403:23, 1414:2, 1416:1, 1428:11, 1441:3, 1455:21, 1465:5</p> <p>two-by-two [1] - 1306:2</p> <p>two-step [2] - 1286:5, 1376:11</p> <p>type [13] - 1286:8, 1315:6, 1356:20, 1356:25, 1362:9, 1362:11, 1438:13, 1439:6, 1439:7, 1439:9, 1439:10, 1439:19, 1462:10</p> <p>types [5] - 1357:14, 1357:20, 1357:21, 1439:21, 1455:22</p> <p>typical [2] - 1340:4, 1340:7</p> <p>typically [1] - 1261:1</p>	<p>unfavorable [1] - 1391:13</p> <p>union [1] - 1425:21</p> <p>Union [1] - 1426:10</p> <p>unit [1] - 1458:6</p> <p>United [7] - 1406:25, 1408:5, 1425:24, 1426:2, 1426:6, 1427:3, 1427:10</p> <p>UNITED [2] - 1256:1, 1256:7</p> <p>universally [6] - 1278:1, 1290:12, 1298:12, 1453:24, 1458:16, 1458:18</p> <p>University [6] - 1258:21, 1259:2, 1259:8, 1259:10, 1270:5, 1411:5</p> <p>unless [1] - 1309:7</p> <p>unlikely [1] - 1321:20</p> <p>unpack [1] - 1407:3</p> <p>unpublished [1] - 1428:17</p> <p>unreliable [1] - 1346:1</p> <p>unusually [1] - 1435:2</p>	<p>upshot [2] - 1448:13, 1465:19</p> <p>upside [1] - 1401:8</p> <p>urban [1] - 1340:7</p> <p>usage [1] - 1280:20</p> <p>USDJ [1] - 1256:9</p> <p>useful [3] - 1333:24, 1458:8, 1458:13</p> <p>user [1] - 1318:5</p> <p>users [8] - 1317:15, 1317:21, 1317:22, 1328:11, 1364:20, 1365:2, 1406:11</p> <p>uses [6] - 1296:25, 1327:19, 1335:22, 1364:4, 1365:2, 1430:19</p> <p>UT [1] - 1321:24</p> <p>uterine [6] - 1280:11, 1402:7, 1403:10, 1403:17, 1442:1, 1442:12</p> <p>uterus [2] - 1280:13, 1379:9</p> <p>utilize [1] - 1399:9</p>
<p>U</p>	<p>U.S [3] - 1256:25, 1407:22, 1426:23</p> <p>U.S.C [1] - 1470:3</p> <p>ultimate [1] - 1409:12</p> <p>ultimately [1] - 1451:13</p> <p>under [12] - 1296:10, 1324:6, 1325:1, 1337:13, 1380:7, 1382:18, 1391:1, 1403:23, 1405:1, 1428:13, 1433:10, 1434:23</p> <p>undergoing [1] - 1372:3</p> <p>underlying [4] - 1283:16, 1287:15, 1393:4, 1466:13</p> <p>undermine [2] - 1449:14, 1457:16</p> <p>underpowered [9] - 1421:11, 1421:25, 1422:8, 1424:2, 1424:8, 1424:12, 1424:18, 1424:20, 1424:21</p> <p>understood [6] - 1262:4, 1272:19, 1437:18, 1438:4, 1442:24, 1466:19</p> <p>undertook [2] - 1262:5, 1365:25</p> <p>unexposed [1] - 1422:20</p>	<p>up [38] - 1263:13, 1275:19, 1283:15, 1285:10, 1288:22, 1297:12, 1300:9, 1302:24, 1310:15, 1314:6, 1315:4, 1335:20, 1370:10, 1372:17, 1372:18, 1388:1, 1394:6, 1394:16, 1395:5, 1396:24, 1397:2, 1401:5, 1401:11, 1413:19, 1428:6, 1428:11, 1445:16, 1448:4, 1450:17, 1450:20, 1451:3, 1451:10, 1452:10, 1453:12, 1458:1, 1459:9, 1461:15, 1463:2</p> <p>up-regulation [1] - 1288:22</p> <p>update [2] - 1415:23, 1416:12</p> <p>updated [1] - 1415:17</p> <p>updating [1] - 1415:19</p> <p>upper [4] - 1291:21, 1292:6, 1301:16, 1306:17</p>	<p>vagina [9] - 1280:4, 1282:6, 1379:2, 1399:6, 1400:15, 1401:3, 1401:5, 1401:8, 1401:12</p> <p>vaginal [7] - 1399:9, 1401:21, 1402:7, 1403:10, 1403:17, 1442:1, 1442:11</p> <p>vague [1] - 1308:20</p> <p>valent [7] - 1360:24, 1361:3, 1361:16, 1362:2, 1362:7, 1362:12, 1362:14</p> <p>variability [2] - 1325:17, 1326:15</p> <p>variable [1] - 1362:21</p> <p>varies [2] - 1264:5, 1362:19</p> <p>various [13] - 1262:11, 1268:5, 1279:19, 1304:11, 1311:12, 1314:1, 1316:5, 1323:16, 1347:15, 1380:7, 1393:23, 1424:5, 1437:25</p> <p>varying [1] - 1455:4</p> <p>vast [1] - 1275:13</p>

Venter [1] - 1280:2	water [8] - 1318:24, 1319:2, 1340:1, 1341:9, 1341:11, 1364:1, 1425:4	1299:20, 1300:8, 1317:7, 1321:16, 1327:2, 1327:6, 1329:23, 1330:1, 1332:22, 1333:13, 1336:16, 1336:18, 1344:20, 1346:14, 1347:20, 1347:23, 1348:3, 1348:4, 1350:16, 1351:19, 1351:21, 1352:20, 1353:7, 1354:9, 1357:6, 1361:22, 1364:9, 1366:16, 1368:3, 1368:25, 1371:18, 1372:14, 1374:4, 1376:24, 1377:19, 1378:21, 1381:2, 1381:17, 1382:1, 1386:18, 1395:1, 1410:18, 1411:12, 1414:12, 1414:15, 1415:8, 1416:3, 1428:8, 1428:11, 1428:16, 1431:3, 1440:3, 1442:20, 1445:14, 1459:7, 1459:12, 1461:15, 1466:21, 1467:9	Witness [1] - 1467:22
ventilation [1] - 1450:14	ways [4] - 1267:23, 1325:9, 1342:9, 1441:2		witness [5] - 1258:10, 1366:6, 1421:14, 1451:10, 1465:16
verifies [1] - 1382:4	weak [6] - 1406:16, 1406:20, 1407:5, 1413:1, 1413:6, 1453:17		WITNESSES [1] - 1468:7
versed [1] - 1410:15	weaknesses [1] - 1393:22		wives [1] - 1349:17
versions [1] - 1416:2	week [1] - 1275:21		WOLFSON [1] - 1256:9
versus [6] - 1264:4, 1266:9, 1266:12, 1278:7, 1313:15, 1361:19	weeks [1] - 1396:23		woman [13] - 1283:8, 1327:19, 1335:21, 1335:23, 1352:16, 1352:25, 1376:18, 1400:22, 1401:7, 1401:8, 1401:11, 1401:25, 1451:23
vertical [1] - 1306:7	Wehner [1] - 1281:18		woman's [5] - 1330:11, 1331:21, 1361:19, 1364:4, 1364:13
via [2] - 1296:13, 1296:17	weigh [2] - 1278:6, 1314:19		women [27] - 1278:21, 1280:10, 1284:19, 1312:1, 1312:3, 1313:15, 1326:7, 1350:5, 1350:10, 1350:21, 1352:14, 1352:25, 1354:18, 1354:22, 1355:11, 1355:24, 1371:5, 1371:24, 1372:3, 1372:19, 1394:4, 1399:5, 1408:4, 1408:9, 1412:12, 1437:17, 1454:15
viable [3] - 1281:22, 1286:10, 1295:15	weighed [1] - 1314:20		word [9] - 1283:4, 1283:5, 1289:12, 1294:19, 1294:21, 1385:9, 1405:20, 1406:6, 1434:21
victim [1] - 1308:15	weight [4] - 1314:18, 1368:1, 1375:16, 1405:16		words [10] - 1266:18, 1309:10, 1320:20, 1331:12, 1339:1, 1344:2, 1348:10, 1356:9, 1356:12, 1382:10
view [4] - 1311:14, 1329:13, 1424:20, 1434:19	weighted [1] - 1375:6		worker [4] - 1324:10, 1324:22, 1325:4, 1466:2
VINCENT [1] - 1256:24	WEIL [1] - 1256:21		workers [1] - 1349:18
Vincent [1] - 1470:8	Weiss [1] - 1430:8		world [2] - 1264:7, 1347:16
Vinnie [1] - 1289:11	welder [1] - 1450:4		wound [1] - 1283:10
violate [1] - 1313:12	welding [6] - 1450:5, 1450:15, 1450:18, 1450:23, 1467:4		write [3] - 1270:7, 1403:24, 1413:20
VIRGINIA [1] - 1256:14	well-conducted [1] - 1455:4		writers [1] - 1340:23
visual [1] - 1422:4	well-described [1] - 1314:21		writes [1] - 1296:10
vitamins [1] - 1364:1	well-designed [1] - 1285:3		writings [2] - 1400:11
vitro [7] - 1261:18, 1287:5, 1287:18, 1287:19, 1290:21, 1297:18, 1388:23	Wera [1] - 1420:11		
vivo [1] - 1261:18	whatsoever [1] - 1352:24		
volume [2] - 1321:12, 1321:17	wheel [1] - 1420:25		
Volume [4] - 1357:5, 1357:6, 1374:7, 1381:15	whole [8] - 1275:3, 1287:16, 1291:24, 1307:9, 1312:16, 1428:6, 1428:8, 1465:18		
VOLUME [1] - 1256:5	widely [1] - 1264:5		
vulvar [5] - 1401:21, 1402:6, 1403:10, 1442:1, 1442:11	WILLIAMS [83] - 1256:20, 1260:12, 1264:17, 1265:10, 1266:6, 1266:17, 1267:13, 1267:24, 1268:13, 1269:8, 1269:12, 1271:5, 1271:7, 1271:11, 1275:25, 1292:16, 1293:4, 1294:8, 1294:11, 1295:16, 1295:19, 1298:18, 1299:3, 1299:10,		
W			
walk [6] - 1288:9, 1302:2, 1305:25, 1310:16, 1310:22, 1446:22	WILLIAMS' [3] - 1267:7, 1294:3, 1444:19		
walked [1] - 1454:25	wise [1] - 1456:9		
walking [3] - 1275:6, 1277:17, 1286:24	WITNESS [18] - 1259:12, 1268:4, 1269:14, 1269:16, 1283:21, 1283:24, 1284:2, 1284:8, 1309:1, 1309:9, 1309:11, 1346:10, 1352:11, 1370:14, 1370:19, 1370:25, 1371:4, 1371:14		
wall [1] - 1302:21			
wants [1] - 1278:19			
warning [1] - 1322:1			
washed [1] - 1305:6			
WASHINGTON [2] - 1256:18, 1257:6			

1400:13
written [3] - 1321:19,
1323:2, 1445:5
wrote [9] - 1325:1,
1325:14, 1325:18,
1340:23, 1356:7,
1405:18, 1416:19,
1433:2, 1433:14
Wu [1] - 1312:23

X

X-ray [1] - 1272:10

Y

year [11] - 1275:19,
1315:20, 1406:25,
1407:22, 1408:1,
1408:8, 1408:10,
1409:21, 1420:9,
1425:9, 1425:11

years [14] - 1259:6,
1268:5, 1279:19,
1286:22, 1289:15,
1302:9, 1303:2, 1318:1,
1395:25, 1396:2,
1437:18, 1450:7,
1458:12, 1460:14

yellow [1] - 1307:3

YORK [1] - 1256:20

yourself [11] - 1261:20,
1267:16, 1326:15,
1326:17, 1339:11,
1347:12, 1348:7,
1369:18, 1378:5,
1411:8, 1411:15

Z

zero [4] - 1330:13,
1330:18, 1330:24,
1331:9

zone [1] - 1450:18